

Federal Register

Wednesday
April 17, 1985

Selected Subjects

Administrative Practice and Procedure
Veterans Administration

Air Pollution Control
Environmental Protection Agency

Alcohol and Alcoholic Beverages
Federal Aviation Administration

Antibiotic Drugs
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Food Grades and Standards
Agricultural Marketing Service

Food Labeling
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Government Employees
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Federal Highway Administration

Motor Vehicle Safety

National Highway Traffic Safety Administration

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Title 3—

Executive Order 12509 of April 14, 1985

The President

Technical Review Group on Inertial Confinement Fusion

By the authority vested in me as President by the Constitution and statutes of the United States of America, including Section 1633 of the Department of Defense Authorization Act, 1985 (Public Law 98-525), and in order to establish an advisory committee to review the inertial confinement fusion program, it is hereby ordered as follows:

Section 1. There is established the Technical Review Group on Inertial Confinement Fusion. The Technical Review Group shall be composed of two members, the Director of the Office of Science and Technology Policy, who shall also serve as Chairman, and the Director of the Office of Energy Research of the Department of Energy.

Sec. 2. (a) The Task Force shall review thoroughly the accomplishments, management, goals, and anticipated contributions of the defense inertial confinement fusion program and shall advise the President and the Congress concerning its findings of fact and recommendations regarding priorities for future work in the inertial confinement fusion program. In conducting its review and recommendations, the Technical Review Group shall contract with an appropriate independent, nationally recognized organization of scientists to study the inertial confinement fusion program and to submit its evaluation to the Technical Review Group for consideration in preparation of its reports.

(b) The Technical Review Group shall submit an interim report to the President and the Committees on Armed Services of the Senate and the House of Representatives before June 1, 1985, and shall submit its final report before May 1, 1986.

Sec. 3. (a) The heads of Executive departments and agencies shall, to the extent permitted by law, provide the Technical Review Group with such information as may be necessary for the effective performance of its functions.

(b) Members of the Technical Review Group shall serve without compensation for their work on the Group.

(c) The Director of the Office of Science and Technology Policy shall, subject to the availability of funds, provide the Technical Review Group with such administrative services, facilities, staff, and other support services as may be necessary.

Sec. 4. The Technical Review Group shall terminate upon the submission of its final report.

Ronald Reagan

THE WHITE HOUSE,

April 14, 1985.

[FR Doc. 85-9353

Filed 4-15-85; 2:35 pm]

Billing Code 3195-01-M

Presidential Documents

Proclamation 5318 of April 15, 1985

Pan American Day and Pan American Week, 1985

By the President of the United States of America

A Proclamation

The countries of the Western Hemisphere are bound together by their humanitarian ideals, their respect for individual liberty, and their yearning for peace and prosperity—goals eloquently expressed in the Charter of the Organization of American States. Just as our Revolution of 1776 was an inspiration for Simon Bolivar and Jose de San Martin, so we in the United States took inspiration from the struggle of our neighbors to be free from foreign domination. We continue to take courage from those great struggles for liberty today, when new forms of tyranny and modern totalitarian systems threaten the peace and security of the Hemisphere, especially in Central America.

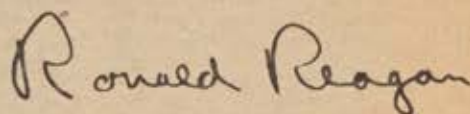
The Organization of American States, embodying the Inter-American System, links together this diverse group of nations, with their Spanish, Portuguese, French, English, African, and Indian heritages. But whatever their creeds, languages, or cultures, the peoples of our Hemisphere are united in the common cause of ending poverty, disease, and illiteracy. The O.A.S. has played a notable role in this cause.

More and more countries of the Hemisphere are turning to democratic institutions to solve political, social, educational, and economic problems. They realize that peace, prosperity, and freedom are best served when the people, faced with a real choice of political parties, freely elect their own governments.

On this Pan American Day of 1985, the people of the United States extend warm greetings to all their neighbors in the Americas and reaffirm their active support for the Organization of American States and the principles for which it stands.

NOW, THEREFORE, I, RONALD REAGAN, President of the United States of America, do hereby proclaim Sunday, April 14, 1985, as Pan American Day, and the week beginning April 14, 1985, through April 20, 1985, as Pan American Week. I urge the Governors of every State of the Union, and the Governor of the Commonwealth of Puerto Rico, and officials of the other areas under the flag of the United States of America to honor these observances with appropriate activities and ceremonies.

IN WITNESS WHEREOF, I have hereunto set my hand this fifteenth day of April, in the year of our Lord nineteen hundred and eighty-five, and of the Independence of the United States of America the two hundred and ninth.



Rules and Regulations

Federal Register

Vol. 50, No. 74

Wednesday, April 17, 1985

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 911

Limes Grown in Florida; Amendment to Container Marking Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule specifies new lime size designations to be used in marking containers of seedless limes based on the number of seedless limes in a ten pound sample. This rule is necessary to prevent misrepresentation of the size of seedless limes in containers, facilitate sales of seedless limes between buyers and sellers, and promote orderly marketing of Florida seedless limes. This action also updates references to the United States Grade Standards for Florida Limes used in this regulation.

EFFECTIVE DATE: April 17, 1985.

FOR FURTHER INFORMATION CONTACT: William J. Doyle, Chief, Fruit Branch, F&V, AMS, USDA, Washington, D.C. 20250, telephone (202) 447-5975.

SUPPLEMENTARY INFORMATION: This action has been reviewed under Secretary's Memorandum 1512-1 and Executive Order 12291 and has been designated a "non-major" rule. William T. Manley, Deputy Administrator, Agricultural Marketing Service, has determined that this action will not have a significant economic impact on a substantial number of small entities.

This final rule is issued under the marketing agreement, as amended, and Order No. 911, as amended (7 CFR Part 911), regulating the handling of limes grown in Florida. The agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674).

The final rule is based upon recommendations and information submitted by the Florida Lime Administrative Committee, established under the marketing agreement and order, and upon other information. Shipments of Florida limes are regulated by pack under § 911.311 Lime Pack Regulation 9 (7 CFR Part 911). The pack regulation, which is effective on a continuing basis, establishes pack and container marking requirements for fresh limes. This action was unanimously recommended by the Florida Lime Administrative Committee.

This action requires the marking of containers of seedless limes with one of seven specified lime size designations. These seven size designations are defined in terms of the number of limes in a ten pound sample. Handlers of limes use several different sizes and weights of containers in shipping limes. The committee reports that handlers currently designate lime sizes by count or number of fruit in the container. The has caused some buyer confusion since the number of limes will vary with the size of the container. In some instances, the number of limes in a container has been misrepresented to the buyer. This action is designed to alleviate this situation by standardizing lime sizes so that the same lime size designation is shown regardless of the size and weight of the container in which the limes are packed. These size designations are currently used by many handlers on a voluntary basis. This action is necessary to facilitate sales between buyers and sellers of limes and promote orderly marketing of Florida seedless limes.

A proposed rule was published in the March 8 issue of the Federal Register (50 FR 9452), with a 15 day comment period. One comment was received from the Florida Lime Administrative Committee. The committee met on March 20, 1985 and voted unanimously to change the requirement that the size be marked on the top and two sides to requiring that the size be marked on two sides only. The committee reports that marking the size on the top of the container would require extensive changes in the packing line for most handlers and increase costs. The final rule adopts the less restrictive size marking requirement as recommended by the committee.

It is hereby found that good cause exists for not postponing the effective date of this regulation until 30 days after

publication in the Federal Register (5 U.S.C. 553) in that a notice of proposed rulemaking concerning this regulation, with an effective date of April 1, 1985 specified, was published in the Federal Register (50 FR 9452) and no objection to that date was received; one comment was filed by the Florida Lime Administrative Committee and the views expressed in that comment have been incorporated in this final rule. Shipments of the current crop of limes are in progress and this regulation should be effective immediately in order to effectuate the declared policy of the act.

List of Subjects in 7 CFR Part 911

Marketing agreements and orders, Limes, Florida.

PART 911—[AMENDED]

The final rule amends paragraphs (a)(1) and (b) in § 911.311 by removing the reference to "7 CFR 2851.1000-2851.1016" and inserting in its place the reference to "7 CFR 51.1000-51.1016" and adding a new paragraph (a)(5) to read as follows:

§ 911.311 Lime Pack Regulation 9.

(a) * * *

(5) No handler shall handle any container of seedless limes, grown in the production area, unless such container is marked on two sides with letters at least one inch in height with one of the size designations shown in column 1 of the following table: *Provided*, that the number of seedless limes in a ten pound sample of a particular size designation, representative of the limes in the container, corresponds to the permissible size range in column 2 of such table for such size designation.

TABLE 1

Column 1 size designations	Column 2 size range
72	68 to 76
63	60 to 66
54	51 to 57
45	46 to 50
42	40 to 44
36	34 to 38
28	27 to 29

* * * * *

(Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674)

Dated: April 11, 1985.

Thomas R. Clark,

Deputy Director, Fruit and Vegetable
Division, Agricultural Marketing Service.

[FR Doc. 85-9185 Filed 4-16-85; 8:45 am]

BILLING CODE 3410-02-M

Farmers Home Administration

7 CFR Parts 1872, 1942, 1944, 1951,
1955 and 1962

Servicing Cases Where Unauthorized Loan or Other Financial Assistance Was Received

Correction

In FR Doc. 85-7809 beginning on page 12989 in the issue of Tuesday, April 2, 1985, make the following correction: On page 12989, in the second column, the first line should read: "EFFECTIVE DATE: May 2, 1985."

BILLING CODE 1505-01-M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 103

Powers and Duties of Service Officers; Availability of Service Records

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule.

SUMMARY: This final rule changes the position title of the Director for Anti-Smuggling to Assistant Commissioner, Anti-Smuggling. This change is made with a view toward more effective Service management.

EFFECTIVE DATE: February 28, 1985.

FOR FURTHER INFORMATION CONTACT: Loretta J. Shogren, Director, Policy Directives and Instructions, Immigration and Naturalization Service, 425 I Street, NW., Washington, D.C. 20536. Telephone: (202) 633-3291.

SUPPLEMENTARY INFORMATION: On March 30, 1983 at 48 FR 13146 the Immigration and Naturalization Service published the reorganization of its central and regional offices as approved by the Attorney General and Congress. The Office of Anti-Smuggling was placed under the direction of the Associate Commissioner for Enforcement with the office being under the immediate supervision of the Director for Anti-Smuggling. Since that time, the position of Director has been changed to Assistant Commissioner for Anti-Smuggling.

Compliance with 5 U.S.C. 553 as to notice of proposed rulemaking and delayed effective date is unnecessary because this rule relates solely to agency organization and management.

In accordance with 5 U.S.C. 605(b), the Commissioner of Immigration and Naturalization certifies that this rule does not have a significant impact on a substantial number of small entities. This order is not a rule within the definition of section 1(a) of E.O. 12291 as it relates to agency organization and management.

List of Subjects in 8 CFR Part 103

Administrative practice and procedure, Authority designation (government agencies), Organization and functions.

Accordingly, Chapter 1 of Title 8 of the Code of Federal Regulations is amended to read as follows:

PART 103—POWERS AND DUTIES OF SERVICE OFFICERS; AVAILABILITY OF SERVICE RECORDS

§ 103.1 [Amended]

In § 103.1, paragraph (c)(4) is revised to read as follows:

- (c) * * *
- (4) Assistant Commissioner for Anti-Smuggling, and
- * * *

(Sec. 103 of the Immigration and Nationality Act, as amended, 8 U.S.C. 1103)

Dated: April 10, 1985.

Raymond M. Kisor,

Associate Commissioner, Enforcement,
Immigration and Naturalization Service.

[FR Doc. 85-9215 Filed 4-16-85; 8:45 am]

BILLING CODE 4410-10-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 85-ANE-13; Amdt. 39-5029]

Airworthiness Directives; Teledyne Continental Motors IO-470 and O-470 Series Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) which requires an inspection for cylinder assemblies with P/Ns 646680A4 and 646680A5 and replacement of exhaust valve P/N 626540 with P/N 637781 in these assemblies. These cylinder assemblies were installed on certain

Teledyne Continental Motors (TCM) new and rebuilt IO-470 and O-470 series engines and sold over the counter in the aftermarket. The AD is needed to prevent possible wear and seizure of the exhaust valve stem caused by incompatible materials and insufficient clearance between the valve stem and its valve guide which, if left uncorrected, could result in total loss of engine power.

DATES: Effective—April 15, 1985.

Compliance Schedule—as indicated in the body of the AD.

Incorporation by Reference—Approved by the Director of the Federal Register on April 15, 1985.

ADDRESSES: The applicable Service Bulletin (SB) M85-3 and Maintenance and Overhaul Manual, Form No. X30022A, may be obtained from:

Teledyne Continental Motors, Aircraft Products Division, P.O. Box 90, Mobile, Alabama 36601, Telephone (205) 438-3411

A copy of the SB is contained in the Rules Docket, located in the Office of the Regional Counsel, New England Region, Federal Aviation Administration, 12 New England Executive Park, Burlington, Massachusetts 01803, and in the Central File Room of the Atlanta Aircraft Certification Office, 1075 Inner Loop Road, College Park, Georgia 30337.

FOR FURTHER INFORMATION CONTACT: Robert R. Goodall, Aerospace Engineer, Propulsion Branch, ACE-140A, Atlanta Aircraft Certification Office, Federal Aviation Administration, 1075 Inner Loop Road, College Park, Georgia 30337, telephone (404) 763-7435.

SUPPLEMENTARY INFORMATION: The FAA has determined that some TCM new and rebuilt IO-470 and O-470 engines and all cylinder assemblies with P/Ns 646680A4 and 646680A5 sold in the aftermarket for installation on these engines were assembled with exhaust valves and valve guides which have material incompatibility and insufficient stem to guide clearance. If left uncorrected, these conditions could cause valve stem wear, oil contamination, valve seizure, and total loss of engine power. Since this condition is likely to exist or develop on other engines or cylinder assemblies of the same type design, an AD is being issued which requires the replacement of the exhaust valves, P/N 626540 with P/N 637781, in all cylinder assemblies with P/Ns 646680A4 and 646680A5 installed on TCM new and rebuilt IO-470 and O-470 series engines and those cylinder assemblies (P/Ns 646680A4 and 646680A5) sold in the aftermarket.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable, and good cause exists for making this amendment effective in less than 30 days.

Conclusion

The FAA has determined that this regulation is an emergency regulation that is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been further determined that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant/major regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation or analysis is not required). A copy of it, when filed, may be obtained by contacting the person identified under the caption "FOR FURTHER INFORMATION CONTACT".

List of Subjects in 14 CFR Part 39

Engines, Air transportation, Aircraft, Aviation safety, Incorporation by Reference.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) is amended by adding the following new AD:

Teledyne Continental Motors: Applies to TCM new and rebuilt engines, IO-470-C, S/Ns 242071 through 242076; 0-470-K, S/Ns 49390 through 49394; 0-470-L, S/Ns 69640 through 69643; 0-470-M, S/Ns 54141 and 54142; 0-470-R, S/Ns S/N 238170, 238171, 238176 through 238197, 2138199 through 238211, 238213, 238215 through 238218, 238223, 238224, 466653 and 466654; 0-470-S S/N 226443, 226444, 226446 through 226457; and all cylinder assemblies P/N 646680A4 and 646680A5 in inventory or installed on engines IO-470-C, 0-470-G, -K, -L, -M, -R, -S since March 1984.

After the effective date of this AD, compliance is required as indicated unless already accomplished:

(a) Compliance required within the next 10 hours time in service for the affected engines with cylinder assemblies having P/Ns 646680A4 and 646680A5 installed.

(b) Compliance is required prior to installation on an engine for uninstalled cylinder assemblies with P/Ns 646680A4 and 646680A5.

To prevent possible valve stem wear, oil contamination, valve seizure, and total loss of engine power, accomplish the following:

(a) Inspect each specified engine and cylinder assembly for the P/N stamped on the base flange of the cylinder.

Note:—This AD applies only to the specified engines and cylinder assemblies having P/Ns 646680A4 and 646680A5.

(1) If an inspection reveals no specified engines or cylinder assemblies in stock, no further action is required by this AD.

(2) If inspection of any of the specified engines reveals no cylinder assemblies with P/Ns 646680A4 or 646680A5, make appropriate engine log book entry stating in effect that this engine has been inspected in accordance with this AD. Return engine to service. No further action is required by this AD.

(3) If inspection of any of the specified engines or aftermarket stock reveals cylinder assemblies having P/Ns 646680A4 or 646680A5, comply with paragraphs (b), (c), (d), (e), and (f).

(b) Remove the cylinder assemblies (P/N 646680A4 and/or P/N 646680A5) from stock or from the engine, as applicable, and replace the exhaust valve, P/N 626540, with P/N 637781 exhaust valve.

Note:—The exhaust valves, gaskets, and seals necessary to accomplish this modification are listed by P/N in TCM SB M85-3, dated February 4, 1985, and can be purchased through TCM distributors.

(c) Inspect the valve guide for any metal transferred from the valve stem. If present, remove using a 1/4-inch diameter by approximately 8-inch long mandrel wrapped with 180 grit crocus paper. Polish the guide only enough to remove the transferred material. After polishing, the guide inside diameter must not exceed the service limit of 0.4405 inch.

(d) Restamp the cylinder assemblies with P/N 646680A7 after replacing the valves and polishing the valve guides, if required.

(e) Return the cylinder assemblies to stock or reinstall on the engine, as applicable.

Note:—Reinstall cylinder assemblies using the procedures outlined in the Maintenance and Overhaul Manual for 0-470 and IO-470 Series Aircraft Engine published by TCM under Form No. X30022A.

(f) Make appropriate maintenance record entry showing compliance with this AD.

Aircraft may be ferried in accordance with the provisions of Federal Aviation Regulations (FARs) 21.197 and 21.199 to a base where the AD can be accomplished.

Upon request, an equivalent means of compliance with the requirements of this AD may be approved by the Manager, Atlanta Aircraft Certification Office, 1075 Inner Loop Road, College Park, Georgia 30337.

The manufacturer's specifications and procedures identified and described in this directive are incorporated herein and made a part hereof pursuant to 5 U.S.C. 552(a)(1). All persons affected by this directive who have not already received this document from the manufacturer may obtain copies upon request to Teledyne Continental Motors, Aircraft Products Division, P.O. Box 90, Mobile, Alabama 36601. These documents also may

be examined at the Office of the Regional Counsel, FAA New England Region, 12 New England Executive Park, Burlington, Massachusetts 01803, and in the Central File Room of the Atlanta Aircraft Certification Office, 1075 Inner Loop Road, College Park, Georgia 30337, weekdays, except Federal holidays, between the hours of 8:00 a.m. and 4:40 p.m.

This amendment becomes effective on April 15, 1985.

(Secs. 313(a), 601, and 603, Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421, and 1423); 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983); 14 CFR 11.89)

Issued in Burlington, Massachusetts, on March 26, 1985.

Robert E. Whittington,

Director, New England Region.

[FR Doc. 85-9241 Filed 4-12-85; 4:01 p.m.]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 83-ASW-30; Amdt. 39-5017]

Airworthiness Directives; Sikorsky Model S-76A Helicopters

AGENCY: Federal Aviation Administration (FAA).

ACTION: Final rule.

SUMMARY: This amendment amends an existing airworthiness directive (AD) which requires frequent repetitive inspections of the vertical pylon on certain Sikorsky Model S-76A helicopters. An approved helicopter modification is available to strengthen the pylon. Inspections of a strengthened pylon are not necessary. Therefore, this amendment excludes these modified helicopters from further AD inspections.

DATES: Effective April 22, 1985.

The incorporation by reference of certain publications listed in this amendment is approved by the Director of the Federal Register as of April 22, 1985.

Compliance: As prescribed in the body of AD.

ADDRESSES: The applicable customer service notice may be obtained from Sikorsky Aircraft, Division of United Technologies, North Main Street, Stratford, Connecticut 06601.

A copy to the customer service notice is contained in the Rules Docket at the Office of the Regional Counsel, Southwest Region, Federal Aviation Administration, 4400 Blue Mound Road, Fort Worth, Texas 76106.

FOR FURTHER INFORMATION CONTACT: Donald F. Thompson, Airframe Section, ANE-152, Boston Aircraft Certification Office, Federal Aviation Administration,

New England Region, 12 New England Executive Park, Burlington, Massachusetts 01803, telephone (617) 273-7113.

SUPPLEMENTARY INFORMATION: This amendment amends Amendment 39-4711 (46 FR 39052), AD 83-17-07, which currently requires a frequent repetitive inspection for cracks in the vertical pylon front spar caps and web on certain Sikorsky Model S-76A helicopters that have attained 2,400 hours' time in service. After issuing AD 83-17-07, the FAA determined that after a specific and optional modification of the vertical pylon has been accomplished, the repetitive inspections specified in the AD are no longer necessary. Therefore, the FAA is amending Amendment 39-4711 by removing the inspection requirement for those helicopters that have incorporated a specific pylon forward and aft spar enforcement modification.

Since this amendment provides for incorporation of an optional design feature which would eliminate an existing repetitive inspection requirement, but does not mandate adoption of the modification, it is found that notice and public procedure hereon are unnecessary and the amendment may be made effective in less than 30 days.

The FAA determined that this amendment could involve up to 230 aircraft with an estimated cost of \$2,800 for each vertical pylon forward and aft spar modification whenever chosen by an operator. Therefore, I certify that this action (1) is not a "major rule" under Executive Order 12291, and (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). A copy of the final evaluation for this action is contained in the regulatory docket. A copy of it may be obtained by contacting the person identified under the caption **FOR FURTHER INFORMATION CONTACT**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety, Incorporation by reference.

Adoption of the Amendment

§ 39.13 [Amended]

Accordingly, pursuant to the authority delegated to me by the Administrator, § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) is amended by amending Amendment 39-4711 (46 FR 39052), AD 83-17-07, by adding the following new paragraph (f):

(f) For helicopters that have been modified in accordance with Sikorsky's Customer Service Notice No. 76-141B, Part 1, paragraphs A-F(1), or Part 2, paragraphs A-

E(1), dated January 15, 1985, vertical stabilizer forward and aft spar reinforcement kits, the inspection requirements in paragraphs (a), (b), and (c) are not applicable.

The manufacturer's specifications and procedures identified and described in this directive are incorporated herein and made a part hereof pursuant to 5 U.S.C. 552(a)(1). All persons affected by this directive who have not already received these documents from the manufacturer may obtain copies upon request to Sikorsky Aircraft, Division of United Technologies, North Main Street, Stratford, Connecticut 06601. These documents also may be examined at the Rules Docket at the Office of the Regional Counsel, Southwest Region, Federal Aviation Administration, 4400 Blue Mound Road, Fort Worth, Texas 76106.

(Secs. 313(a), 601, and 603, Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421, and 1423); 49 U.S.C. 106(g), (Revised, Pub. L. 97-449, January 12, 1983); 14 CFR 11.89)

This amendment becomes effective April 22, 1985.

This amendment amends Amendment 39-4711 (46 FR 39052), AD 83-17-07.

Issued in Fort Worth, Texas, on March 19, 1985.

C.R. Melugin, Jr.,

Director, Southwest Region.

[FR Doc. 85-9240 Filed 4-15-85; 9:22 am]

BILLING CODE 4910-13-M

FEDERAL TRADE COMMISSION

16 CFR Parts 300 and 303

Amendment to Rules and Regulations Under the Wool Products Labeling Act of 1939 and Textile Fiber Products Identification Act

AGENCY: Federal Trade Commission.

ACTION: Notice of final rulemaking.

SUMMARY: Title III of Pub. L. 98-417 amended the Wool Products Labeling Act of 1939 (Wool Act) (15 U.S.C. 68) and the Textile Fiber Products Identification Act (Textile Act) (15 U.S.C. 70) effective December 24, 1984. On November 13, 1984, the Commission published a notice of rulemaking (49 FR 44913) that proposed amendments to the rules and regulations under each Act to reflect the amendments to these Acts. Written comments were invited until December 13, 1984. Approximately seventy-one comments were received and placed on the public record. This notice contains the statement of basis and purpose for the amendments and the text of the rules and regulations as amended.

EFFECTIVE DATE: Title III of Pub. L. 98-417 became effective on December 24, 1984. The amended rules and regulations will become effective on and after May 17, 1985.

ADDRESS: Requests for copies of the amendments to the rules and regulations and the statement of basis and purpose should be sent to Public Reference Branch, Room 130, Federal Trade Commission, 6th and Pennsylvania Ave., NW., Washington, D.C. 20580.

FOR FURTHER INFORMATION CONTACT: Earl Johnson, Federal Trade Commission, 6th and Pennsylvania Ave., NW., Washington, D.C. 20580. Tel: (202) 376-2891.

SUPPLEMENTARY INFORMATION:

Statement of Basis and Purpose

I. Introduction

II. The Amended Rules

A. Country of Origin

1. Origin of Imported Products
2. Origin of Domestic Products

B. Location of the Label

C. Labeling Packaged Products

D. Origin in Mail Order Catalogs and Promotional Materials

E. Other Rule Changes

1. Wool Act § 300.3 and Textile Act § 303.16.
2. Wool Act § 300.5 and Textile Act § 303.15.
3. Wool Act § 300.10.

III. Regulatory Flexibility Act

IV. Paperwork Reduction Act

V. Effective Date

Statement of Basis and Purpose

I. Introduction

The Wool Products Labeling Act of 1939 was enacted by Congress for the expressed purpose of protecting producers, manufacturers, distributors and consumers from the unrevealed presence of substitutes and mixtures in spun, woven, knitted, felted or otherwise manufactured wool products, and for other purposes.¹ Basically, the Act required that each wool product contain a stamp, tag or label showing the fiber content and the name of the manufacturer or the name of someone in the line of distribution of that product.²

The Textile Fiber Products Identification Act was enacted by Congress in 1958 with the expressed purpose of protecting producers and consumers against misbranding and false advertising of the fiber content of textile fiber products, and for other purposes.³ Like the Wool Act, this Act

¹ Pub. L. 850, 76th Cong., 54 Stat. 1128 (1939), 15 U.S.C. 68.

² 15 U.S.C. 68b.

³ Pub. L. 85-897, 72 Stat. 1717 (1958), 15 U.S.C. 70.

basically required each textile product to contain a stamp, tag or label showing the fiber content and the name of the manufacturer or someone in the line of distribution of the product.⁴ In addition, the Textile Act required that the label contain the name of the country of origin if the product was imported.⁵

Under each of the Acts the Federal Trade Commission was authorized and directed to issue such rules and regulations as may be necessary for their administration and enforcement.⁶ Regulations under the Wool Act were first issued effective July 15, 1941⁷ and regulations under the Textile Act were made effective March 3, 1960.⁸

On September 24, 1984, amendments to both Acts were enacted to become effective 90 days thereafter, or on December 24, 1984.⁹ The Wool Act was amended to require imported products to be labeled with the country of origin. Both the Textile and Wool Acts were amended to require domestically manufactured products to be labeled with the country of origin. The Senate Committee, in a report on the legislation that became Public Law 98-417, stated that the objective of the legislation was to clarify and improve country of origin labeling requirements for textiles and to increase consumer awareness at the time of purchase.¹⁰

In addition to the amendments requiring the disclosure of the country of origin, both Acts were amended to require:

(1) The country of origin disclosure to be placed in the neck of garments having necks, or for garments without necks, on a conspicuous spot on the inside or on the outside of the product;

(2) All products to be separately labeled, except hosiery in a retail package;

(3) All packages, in addition to the products, to be labeled unless the packaging is transparent and the individual product label can be seen through the package; and

(4) Mail order catalogs and mail order promotional materials to disclose in the description of each textile and wool product whether the product is made in U.S.A., imported or both.¹¹

On November 13, 1984, the Commission published a notice of proposed rulemaking in the Federal

Register¹² containing alternative procedures for labeling domestic origin and questions relating to the alternatives. The public was asked to comment in writing by December 13, 1984. In response to its request for comment, the Commission received approximately 71 comments and placed these on the public rulemaking record.

II. The Amended Rules

In this section each of the four major aspects of Pub. L. 98-417, i.e., country of origin, location of the label, labeling of packaged products, and country of origin information in printed mail order advertising, is separately discussed. In each subsection, the discussion begins with a description of the statutory changes to the Textile and Wool Acts. The discussion then turns to the proposals and questions raised by the Commission regarding how to implement the changes. Next, the major relevant comments on the issues are discussed. The discussion concludes with an explanation of the regulatory provision adopted by the Commission.

A. Country of Origin

Prior to the passage of Pub. L. 98-417, the disclosure of the country of origin of imported goods was mandated only for goods covered under the Textile Act.¹³ For imported goods covered under the Wool Act, the Commission had required the disclosure of foreign origin under Section 5 of the FTC Act.¹⁴ Under Section 5, the Commission also had required disclosure of foreign origin for other imported products such as machinery.¹⁵ Additionally, the Commission had advised importers that a product partially made in a foreign country and partially made in the U.S.A. must have a label disclosing that the product was made in the U.S.A. and that it contained imported components.¹⁶ Prior to the enactment of Pub. L. 98-417 there was no requirement to disclose the country of origin of goods made entirely in the United States, although this information could be voluntarily disclosed.¹⁷

1. *Origin of Imported Products.* Pub. L. 98-417 amends the Wool Act to require the disclosure of country of origin on labels for imported wool products.¹⁸ As

a result, the Wool Act's country of origin disclosure requirement now parallels the requirement under the Textile Act for labeling imported products with the country of origin.¹⁹ The U.S. Customs Service (Customs) of the U.S. Department of Treasury administers two Acts that also require all imported textile and wool products to be labeled with the country of origin.²⁰ Under those Acts, a single country of origin is used for the purpose of assessing tariffs, enforcing quotas and marking the products. In the past, regulations under the Textile Act have paralleled the regulations issued by Customs.²¹

These final regulations do not change current requirements under the Textile Act for disclosing the country of origin of imported goods.²² The regulations under the Wool Act for imported wool products have been drafted to implement this statutory amendment to this Act and to parallel the regulations under the Textile Act.²³ Some of the comments on these regulations requested that the Commission adopt a policy statement that the regulatory scheme under the Textile and Wool Acts with respect to country of origin on imported products is intended to be consistent with Customs regulations.²⁴ Other comments requested that the Commission confirm that the amended rules will not affect the labeling of "807" materials.²⁵ To the maximum extent consistent with the legislative intent, the Commission intends the final regulations for the disclosure of the country of origin of imported textile and wool products, including those under the 807 program, to be construed in a manner consistent with Customs regulations.²⁶

2. *Origin of domestic products.* Pub. L. 98-417 amends both the Textile and Wool Acts to mandate, for the first time, the disclosure of the country of origin for domestic products. The Senate Committee Report on the legislation that eventually became Pub. L. 98-417 states that the amendment adding a requirement for country of origin for

⁴ 15 U.S.C. 70b.

⁵ *Id.*

⁶ 15 U.S.C. 68d and 15 U.S.C. 70e.

⁷ 6 FR 3426 (1941). Also see 16 CFR Part 300.

⁸ 24 FR 4460 (1959). Also see 16 CFR Part 303.

⁹ Title III, Pub. L. 98-417, 98 Stat. 1585 (1984).

¹⁰ S. Rep. 529, 98th Cong. 2d Sess. (1984).

¹¹ *Supra*, Note 9.

¹² 49 FR 44913 (1984).

¹³ 16 CFR 303.33 (1984).

¹⁴ 16 CFR 300.25(c) (1984). (see note following this section).

¹⁵ See 16 CFR 15.221.

¹⁶ See 16 CFR 15.282 and 15.307 (1984).

¹⁷ See 16 CFR 15.315 and 15.326 (1984).

¹⁸ *Supra*, Note 9 at section 304.

¹⁹ 15 U.S.C. 70b.

²⁰ Tariff Act of 1930, 19 U.S.C. 86 and Agriculture Act of 1956, 7 U.S.C. 1854.

²¹ Compare 19 CFR Part 134 (1984) and 16 CFR 303.33 (1984).

²² 16 CFR 303.33 (1984).

²³ See § 300.25a as amended.

²⁴ FTC Public Record 204-17-1, Comments, Pages 119, 128, 242, 311.

²⁵ "807" materials are textile or wool products assembled and sewn together in a foreign country of components that came from the United States. The finished products are given special tariff treatment under Item 807.00 of the Tariff Schedules of the United States, 19 U.S.C. 1202.

²⁶ See 19 CFR Part 134 and 19 CFR 10.22.

domestic products is intended to be consistent with current FTC country of origin labeling requirements.²⁷

The Commission's proposed regulations implementing this statutory amendment codified FTC advisory opinions. The proposed regulations required: (1) items entirely made in the U.S.A. to be labeled with "Made in USA"; (2) items made in the U.S.A. using imported materials to be labeled with that fact, e.g., "Made in U.S.A. of fabric from _____"; and (3) items made partially in a foreign country and partially in the U.S.A. to disclose those facts, e.g., "Assembled and sewn in U.S.A. of components made in _____".

The Commission also published an alternative set of proposed regulations and posed several questions concerning these alternatives.²⁸

Comments on the proposed regulations and the alternatives that two of the principal sponsors of the Bill submitted, emphasized that the Senate Committee Report language stated that the amendments were intended to be consistent with existing FTC country of origin labeling requirements. The comments also pointed out that advisory opinions issued by the Commission in the past have required products of mixed domestic and foreign origin to specify that the product was made in the United States of imported materials. The comment further stated that the intent of Congress to codify existing Commission precedent in determining appropriate labeling requirements was also articulated in the hearings conducted by the House Committee.²⁹

Several other comments proposed that the Commission's regulations adopt the substantial transformation test, which was proposed by the Commission as an alternative regulation and is used by Customs for determining a single country of origin for an imported product.³⁰ Still other comments favored using the proposed alternative "Principally made in the USA," which was another of the proposed alternatives published for comment.³¹ However, other comments noted that such a statement would be vague and uninformative. The comments also noted that a proposed test for determining where the product was principally made, i.e., where more than 50% of the value was added, would be difficult to use.³²

Comments filed by the American Fiber Textile Apparel Coalition (AFTAC) recommended that the regulations modify existing precedent slightly, by requiring only a statement of origin such as "Made in USA of imported cloth."³³ Several other comments also favored a simplified disclosure, stating that disclosing the identity of the individual countries, in which imported components of American made goods originated, would entail substantial additional costs to maintain and properly dispense large inventories of labels.³⁴ Similarly, the comment from two of the principal sponsors of the legislation stated the use of "imported" for goods of mixed origin would not be inconsistent with Congressional intent and would preserve the basic goal of the Act. Their comment recommended adoption of the "Made in USA of imported fabric" approach.³⁵

Other comments addressed the Commission's discussion regarding how far back in the manufacturing process the Commission would look to determine whether goods made in the United States contain foreign components. In the proposed regulations the Commission stated that it would look at where the cloth or yarn used in the manufacturing process was made.³⁶ Some comments recommended that this standard be clarified to indicate that each manufacturer would only have to look back one step to determine the country of origin, e.g., yarn manufacturers would look to the fiber source, cloth manufacturers to the yarn source, and garment manufacturers to the cloth or yarn source.³⁷

Another group of comments addressed the question raised in the proposed regulations, regarding whether items excluded by Section 12 of the Textile Act, such as trim, thread and linings for structural purposes, should be excluded when determining the origin of goods.³⁸ The comment filed by two of the principal sponsors of this legislation noted that the Senate Report stated that the labeling provisions of the legislation do not apply to goods not covered by the Textile Act. The comment then stated that given this language, these excluded items should not be included in origin determinations.³⁹ The same treatment

applies to items excluded under a similar exemption provision in the Wool Act.⁴⁰

Comments were also received from the United States Customs Service concerning products partially made in a foreign country and partially made in the United States. Customs commented that its regulations may be interpreted to require that the largest component or part of an unfinished product entering the United States be marked with the foreign country of origin in cases which Customs determines that substantial transformation had taken place abroad.⁴¹ Customs noted that its required label might conflict with the Commission's proposed label requirements, i.e., Customs' label with a single country of origin based on substantial transformation compared to an FTC required label disclosing the foreign and domestic aspects of disclosure.

After considering the comments, the statute, and the legislative history and intent, the Commission has decided to adopt final regulations under the Textile Act and Wool Act that provide for three different categories of domestic origin disclosures.⁴² First, for products made entirely in the United States, the regulation provides that the words "Made in USA" or some other clear and equivalent term must be used. Thus, terms such as "Product of USA", "Crafted with pride in USA", "Tailored in USA", "Manufactured in USA", "Made in New York, USA" and other equivalent markings are acceptable.⁴³

Second, for products made in the United States using foreign materials, the regulation requires a disclosure that the product was, for example, "Made in USA of imported fabric," or equivalent terms. Finally, for products partially manufactured in the United States and partially manufactured in a foreign country, the regulation requires a disclosure that the product was, for example, "Sewn in USA of imported components" or a similar disclosure.

For all the categories, the Commission is only requiring that the manufacturer go back one manufacturing step to determine origin. Thus, a manufacturer of yarn would look back to the source of its fiber. A manufacturer of cloth would look back to the source of its yarn and the garment manufacturer would look back to the source of the yarn in garments that are knitted or to the

²⁷ Supra, Note 10 at section 2.

²⁸ Supra, Note 12 at page 44917.

²⁹ Supra, Note 24 at page 54.

³⁰ Supra, Note 24 at pages 34, 37, 41, 47, 65, 193, 207, 219, 305.

³¹ Supra, Note 24 at pages 128, 170, 252, 274, 276.

³² Supra, Note 24 at pages 119, 272, 296, 303.

³³ Supra, Note 24 at page 311.

³⁴ Supra, Note 24 at pages 18, 34, 193, 242.

³⁵ Supra, Note 24 at page 54.

³⁶ Supra, Note 12, page 44914.

³⁷ Supra, Note 24 at pages 242, 311, 318.

³⁸ Supra, Note 12 at question 3.

³⁹ Supra, Note 24 at page 54.

⁴⁰ 15 U.S.C. 68b (d).

⁴¹ Supra, Note 24 at page 189.

⁴² See Amendments § 300.25a and § 303.33.

⁴³ See Amendments § 300.25a(a)(2) and § 303.33(a)(2).

source of the cloth. Additionally, in determining origin, materials that are otherwise excluded under the Acts do not have to be considered.

For the last two categories of products (i.e., those having both domestic and imported components or aspects of manufacturer to be disclosed), the regulations permit the foreign components or manufacturing operation to be disclosed by using the general term imported or similar terms rather than specifying the foreign country or countries involved.

Similarly, in the last two categories, if the country of origin disclosure required by the Customs Service appears in the neck of the product, that disclosure would also satisfy the Commission's requirement that the country of origin be disclosed in the neck of the product.

B. Location of the Label

The Textile and Wool Acts, as amended by Pub. L. 98-417, now state that the required label must be located in the inside neck of a garment that has a neck, midway between the shoulder seams.⁴⁴ According to the legislative history, the purpose of this requirement is to standardize the location of this information.⁴⁵ Other provisions of the existing regulations state that all information required to be disclosed by the Act must be disclosed in one place.⁴⁶ The Commission proposed an amended regulation under each Act that mandated location of the label in the neck of garments with a neck midway between the shoulder seams. Under the proposed regulation labels for other garments would be located in a conspicuous spot on the inside or outside of the garment.⁴⁷

Many comments noted that the center of the back of the neck was the common location for the brand label and that displacement of the brand label could cause a serious hardship on established sales practices.⁴⁸ They suggested that the origin label be allowed to be located adjacent to the brand label. Other comments stated that requiring all the information to be placed in the neck also could cause that area to be crowded or be unsightly.⁴⁹ The comments suggested permitting the information to be separated, i.e., allowing the country of origin to be disclosed in the neck alone as long as the other required information, e.g., fiber

content and name of the company or RN, was located elsewhere on the garment.

Comments submitted by two of the principal sponsors of the legislation indicated the underlying goal of the location requirement was to standardize the location of the country of origin disclosure so that consumers could find the information quickly and easily. The comment further stated that to the extent the location requirement would displace other label information, the legislation's goal would be satisfied if the origin label was placed immediately next to the other label, as long as it was conspicuous to the consumer.⁵⁰

On the basis of the information provided by all the comments, the Commission has added two provisos to the final regulations requiring the country of origin information to be disclosed on a label on the inside center of the neck. The first proviso permits the required disclosures of origin, fiber content, and name of the manufacturer or RN to be placed in close proximity to a label such as a brand label already affixed to the inside center of the neck, providing the required label remains conspicuous to the consumer. This means that the required label should not be placed so far from the center of the neck that it can not be seen as readily as the label in the center neck position. This approach is also consistent with the Customs Service requirement that origin information be placed in the immediate area of the neck.

A second proviso allows the manufacturer to put all the required information, i.e., origin, fiber content, name or RN of the manufacturer, on a hang tag or a label attached to a conspicuous place on the inside or outside of the garment, provided a label with country of origin appears on the inside neck either in the center or just adjacent to the center label. Thus, the Congressional purpose of providing a standard location for the country of origin is preserved, the crowding of other information in the neck area is alleviated, and the pre-existing requirement that all required information appear on the label together, is retained.⁵¹

C. Labeling Packaged Products

Prior to the amendments, the Textile Act provided that a label was not required on products in a package if (1) the products were intended for sale to the ultimate consumer in such package, (2) the package had a label containing

the required information regarding the products and (3) the information on the label was equally applicable to each product in the package.⁵² Pub. L. 98-417 alters this provision to make it only applicable to hosiery products, but extends the exemption to hosiery under the Wool Act as well as the Textile Act.

The Commission's proposed regulations implemented the amended statute by requiring that all products covered by the Textile and Wool Acts, except hosiery in a package as described above, bear the required label.⁵³ Further, as the amended Acts provide, the proposed regulations required any package of textile or wool products intended for sale to the ultimate consumer to be labeled with the required information unless the information pertaining to the products can be clearly seen through the packaging.⁵⁴

Two comments stated that the term "package" as used in the proposed rules could be mistakenly interpreted to include shipping packages and the dust covers that are used to protect hanging garments until they are put on display by the retailer.⁵⁵ Another comment stated that table linens were commonly packaged with all information on the package or on a label that was slipped inside transparent packaging. The comment suggested that an exemption be granted from attaching a label to the product for this type of packaging.⁵⁶

The Commission's final amended regulations emphasize that the type of package that is required to be labeled is one which is intended to remain unbroken and intact until sale to the ultimate consumer.⁵⁷ Thus, packaging or wrapping used only for shipping or delivering packages to consumers or packaging that is used as a protective cover until the product is put on display for retail sale is not the type required to be labeled. As to the suggestion that exemptions be granted for other types of packaging, the Commission notes that the Senate Committee report states that the Committee intended the exception to individual product labeling to apply only to hosiery.⁵⁸

D. Origin in Mail Order Catalogs and Promotional Materials

Pub. L. 98-417 amended both the Textile and Wool Acts to mandate that

⁴⁴ Supra, Note 9 at section 303 and section 305.

⁴⁵ Supra, Note 10 at Section 4.

⁴⁶ See 16 CFR 300.10 and 303.16 (1985).

⁴⁷ 49 FR 44913, 44916, 44918 (1984).

⁴⁸ Supra, Note 24 at pages 20, 80, 82, 133.

⁴⁹ Supra, Note 24 at pages 45, 47, 85, 119, 128, 182, 193, 237, 311.

⁵⁰ Supra, Note 24 at page 54.

⁵¹ See Amendments at § 300.5(b) and § 303.15(b).

⁵² 15 U.S.C. 70b (e).

⁵³ Supra, Note 9 at section 302 and section 306.

⁵⁴ Id.

⁵⁵ Supra, Note 24 at pages 219, 266.

⁵⁶ Supra, Note 24 at pages 186.

⁵⁷ See Amendments § 300.15 and § 303.28.

⁵⁸ Supra, Note 10 at Section 3.

each description of a textile or wool product contained in a mail order catalog or in mail order promotional material must contain a clear and conspicuous statement that such product is processed or manufactured in the United States of America, or imported or both.⁶⁸

In addition to implementing this requirement, the Commission's proposed regulations included a definition of "mail order catalog" and "mail order promotional material."⁶⁹ The proposed regulations also permitted other words or phrases with the same meaning to be used in place of made in USA, imported or both.⁷⁰ Further, the Commission posed two questions concerning this requirement. First, whether the disclosure "Made in USA and imported" should be allowed for goods made in USA with imported materials, and for goods partially made in a foreign country and partially made in the U.S.A.⁷¹ Second, whether general disclaimers should be permitted as alternatives to putting a disclosure in the description of each product.⁷²

In response to the first question, a number of comments favored the use of "Made in USA and Imported" for goods made in the U.S.A. out of imported materials, and for goods partially made in the U.S.A. and partially made in a foreign country.⁷³ Comments from two of the principal sponsors of the legislation noted that using the term "Made in USA and Imported" to convey mixed origin may be confusing to consumers. The comment suggested that the Commission consider requiring a legend in each catalog to explain the meaning of the origin terms until consumers became familiar with their meanings.⁷⁴

In response to the second question, a number of comments supported the use of general disclaimers.⁷⁵ Two comments, however, stated that the only way to transmit effectively the origin information of each product was to put it in each description.⁷⁶ The comment of the two principal sponsors of the legislation noted that the statutory language expressly requires the origin disclosure to be in each product description that the legislative history

supporting this requirement is very clear.⁷⁷

Finally, two comments suggested clarifying the definitions of "mail order catalog" and "mail order promotional material" to make clear that a general advertisement does not fall within the Act simply because some consumer may make purchases by telephone from the store placing the advertisement.⁷⁸

The Commission's final regulations containing definitions of the terms "mail order catalog" and "mail order promotional material" have been clarified to indicate that the statute and regulations cover advertising that solicits the retail buyer to purchase a product by telephone, mail or some other similar method without first examining that product.⁷⁹ The requirement to disclose the origin of the product does not apply to regular advertising that is used solely to attract the retail buyer to the store to purchase the product. Additionally, the definitions now make clear that the requirement to disclose origin information in mail order advertising applies only to printed advertising that is going to retail consumers. The requirement does not apply to advertising by manufacturers or wholesalers that is meant only for retailers.

The final regulations also implement the statutory requirement that each description contain a clear and conspicuous statement that the product was made in the U.S.A., imported or both.⁸⁰ Although general disclosures of the origin of all products in the mail order catalog or any part thereof are permissible, such general statements or disclaimers do not satisfy the requirements of the Act or the regulations. The regulations also provide that words or phrases other than "Made in USA" or "Imported" may be used provided they have the same meaning. Further, the regulations also indicate that the origin statement used in mail order materials must be consistent with the origin labeling on the product being advertised. For example, a product labeled "Made in USA of imported fabric" could be advertised as "Made in USA and imported," "Made in USA of imported fabric," "Made in USA of (X Country) fabric" or by other words of similar meaning; but "Made in USA" alone would be inconsistent and therefore prohibited.

Because the required disclosures in each product description are extremely short and not necessarily self-

explanatory, it is important that the permitted terms be used in a clear and consistent manner. For example, "Made in USA and Imported" should be used to indicate partial manufacture in USA and partial manufacture in a foreign country, while "Made in USA or Imported" should be used to reflect that a product was being obtained both from a domestic source and a foreign source. To assist consumers, particularly at the outset, the Commission strongly encourages mail order advertisers to include a legend in their advertising explaining the meaning of their country of origin disclosures.

E. Other Rule Changes

A few minor changes to other regulations under both the Wool and Textile Acts were necessary to ensure all regulations correspond with the requirements of the amendments to these Acts. These minor changes are briefly explained below.

1. *Wool Act § 300.3 and Textile Act § 303.16.* Each of these sections lists the required information that must appear on the label, e.g., fiber content, name or RN of the manufacturer, and in the case of the Textile Act, origin of imported products. In addition to the information previously required, the final regulations now list the origin of domestic products, for the Textile Act, and origin of imported and domestic products under the Wool Act as required information.

2. *Wool Act § 300.5 and Textile Act § 303.15.* Subsection (a) of each of these regulations now makes it clear that every product, whether packaged or unpackaged, must have a label bearing the required information. The exemption for hosiery under certain packaging conditions is contained in subsection (c) of each rule.

3. *Wool Act § 300.10.* This rule contains an example of the information the Act requires to be disclosed. Until now, the Wool Act did not require disclosure of the country of origin. Therefore, the country of origin disclosure has been added to the example in this rule.

III. Regulatory Flexibility Act

In publishing the proposed amendments, the Commission determined that the provisions of the Regulatory Flexibility Act⁷² requiring an initial regulatory analysis were not applicable to the amendments because the regulations do not appear to have a significant economic impact on a substantial number of small entities.⁷³

⁶⁸ Supra, Note 9 at section 303 and section 305.

⁶⁹ Supra, Note 12 at page 44918 and 44918.

⁷⁰ Supra, Note 12 at page 44917 and 44918.

⁷¹ Supra, Note 12 at page 44918.

⁷² Id.

⁷³ Supra, Note 24 at pages 170, 266, 318.

⁷⁴ Supra, Note 24, at page 54.

⁷⁵ Supra, Note 24 at pages 60, 61, 133, 170, 193, 219, 266, 272, 280, 296, 324.

⁷⁶ Supra, Note 24 at pages 119, 318.

⁷⁷ Supra, Note 24 at pages 54, 346.

⁷⁸ Supra, Note 24 at pages 191, 193.

⁷⁹ See amendments § 300.1 and § 303.1.

⁸⁰ See amendments § 300.25b and § 303.34.

⁷² 5 U.S.C. 603, 604.

⁷³ Supra, Note 12 at Section C.

The Commission noted that the economic costs are primarily statutorily imposed and the Commission's amendments impose few, if any, independent additional costs. In light of the above, it was certified under the provisions of section 3 of the Regulatory Flexibility Act⁷⁴ that the proposed regulations would not have a significant economic impact on a substantial number of small entities.

The Commission requested comments on the effects of these amendments and asked for numerical estimates if the amendments were believed to affect costs, profitability, competitiveness, or employment in small entities. The comments, however, appear to address the compliance obligations that have been statutorily, rather than administratively, imposed, noting generally that compliance could be burdensome. On the basis of all the information before it, the Commission has determined the final regulations will not have a significant economic impact on a substantial number of small entities. Consequently, the Commission concludes that a final regulatory flexibility analysis is not required and has filed a certificate with the Small Business Administration to that effect.

IV. Paperwork Reduction Act

In the publication of the proposed amendments, the Commission noted that the amended rules contain provisions that constitute information collection requirements under the Paperwork Reduction Act.⁷⁵ Consequently, a supplement to existing clearances was submitted to the Office of Management and Budget.⁷⁶ The supplement was approved by OMB on December 4, 1984.⁷⁷

V. Effective Date

Title III of Pub. L. 98-417 amending the Textile and Wool Labeling Acts became effective on December 24, 1984. Therefore, all textile and wool products covered by these Acts that enter production on or after December 24, 1984 must be labeled in accordance with the amended Acts. All mail order catalogs and mail order promotional materials that are prepared and sent to the printer on or after December 24, 1984 must contain the origin information as required by the amended Acts.

These amended regulations become effective on May 17, 1985. They apply to all textile and wool products covered by the Acts that enter production on or after that date and all mail order catalogs and mail order promotional material prepared and sent to the printer on or after that date.

List of Subjects

16 CFR Part 300

Labeling, Textile, Trade practices, Warranties, Wool.

16 CFR Part 303

Labeling, Textile, Trade practices.

Accordingly, it is proposed that Chapter I of 16 CFR Part 300 be amended as follows:

Authority: 15 U.S.C. 68 *et seq.* and 15 U.S.C. 70 *et seq.*

PART 300—RULES AND REGULATIONS UNDER THE WOOL ACT

1. In § 300.1, paragraphs (g), (h) and (i) are added as follows:

§ 300.1 Terms defined.

* * *

(g) The term *United States* means the several States, the District of Columbia, and the territories and possessions of the United States.

(h) The terms "mail order catalog" and "mail order promotional material" mean any printed materials used in the direct sale or direct offering for sale of wool products that are distributed or shown to ultimate consumers and solicit the ultimate consumers to purchase such wool products by mail, telephone or some other method without examining the actual product purchased.

(i) The terms label, labels, labeled, and labeling mean the stamp, tag, label, or other means of identification, or authorized substitute therefore, required to be on or affixed to wool products by the Act or Regulations and on which the information required is to appear.

2. In § 300.3 add paragraph (a)(4) as follows:

§ 300.3 Required label information.

(a) * * *

(4) The name of the country where the wool product was processed or manufactured.

* * *

3. Section 300.5 is revised to read as follows:

§ 300.5 Required label and method of affixing.

(a) A label is required to be affixed to each wool product and, where required, to its package or container in a secure

manner. Such label shall be conspicuous and shall be of such durability as to remain attached to the product and its package throughout any distribution, sale, resale and until sold and delivered to the ultimate consumer.

(b) Each wool product with a neck must have the label affixed to the inside center of the neck midway between the shoulder seams *provided*, however, that the required label may appear in close proximity to another label affixed to the inside center of the neck as long as the required label remains conspicuous to the consumer and, *provided further*, that if the country of origin is disclosed on a label affixed to the inside center of the neck or in close proximity, the label containing the country of origin, fiber content and RN or name of the company may appear in another conspicuous location on the inside or on the outside of the garment. All other wool products shall have the label affixed to a conspicuous spot on the inner side of the product or in a conspicuous place on the outside of the product.

(c) In the case of hosiery products, this section does not require affixing a label to each hosiery product contained in a package if, (1) such hosiery products are intended for sale to the ultimate consumer in such package, (2) such package has affixed to it a label bearing the required information for the hosiery products contained in the package, and (3) the information on the label affixed to the package is equally applicable to each wool product contained therein.

4. In § 300.10 paragraph (a) is revised to read as follows:

§ 300.10 Arrangement of label information.

(a) All items or parts of the information required to be shown and displayed in the label of the product, shall be set forth consecutively and separately on the outer surface of the label, in immediate conjunction with each other, and in type or lettering plainly legible and conspicuous, and all parts of the required fiber content information shall appear in type or lettering of equal size and conspicuousness; such as for example:

Distributed by:
John Q. Doe Co., Inc.,
New York, N.Y.

Made of
60% WOOL
40% RECYCLED WOOL
EXCLUSIVE OF ORNAMENTATION

Made in U.S.A.

provided, however, that the required name or registered identification number may appear on the reverse side

⁷⁴ 5 U.S.C. 605(b).

⁷⁵ *Supra*, Note 12 at Section D.

⁷⁶ See OMB Clearances Nos. 3084-0052 and 3084-0053.

⁷⁷ Notice of Correction Made By OMB to Carl Hevener, Federal Trade Commission, dated Dec. 4, 1984.

of the label if it is plainly legible, conspicuous and accessible. On products as to which sectional disclosure is used, an additional non-deceptive label may be used showing the complete fiber content information with percentages as to a particular section or area of the product and specifying the section or area referred to.

5. Section 300.15 is revised to read as follows:

§ 300.15 Labeling of containers or packaging of wool products.

When wool products are marketed and delivered in a package which is intended to remain unbroken and intact until after delivery to the ultimate consumer, each wool product in the package, except hosiery, and the package shall be labeled with the required information. If the package is transparent to the extent it allows for a clear reading of the required information on the wool product, the package is not required to be labeled.

§ 300.25 [Amended]

6. Section 300.25 is amended by removing the last four words in the title and removing paragraph (c) and the note that follows.

7. Section 300.25a is added as follows:

§ 300.25a Country where wool products are processed or manufactured.

(a) In addition to the other information required by the Act and Regulations:

(1) Each imported wool product shall be labeled with the name of the country where such imported product was processed or manufactured;

(2) Each wool product completely made in the United States of materials that were made in the United States shall be labeled using the term "Made in U.S.A." or some other clear and equivalent term.

(3) Each wool product made in the United States, either in whole or part, of imported materials shall contain a label disclosing these facts; for example:

"Made in USA of imported fabric"

or

"Knitted in USA of imported yarn" and

(4) Each wool product partially manufactured in a foreign country and partially manufactured in the United States shall contain on the label the following information:

(i) The manufacturing process in the foreign country and in the USA; for example:

"Imported cloth, finished in USA",

or

"Sewn in USA of imported components or

"Made in (foreign country), finished in USA"

(ii) When the U.S. Customs Service requires an origin label on the unfinished product, the manufacturing processes as required in paragraph (a)(4)(i) of this section or the name of the foreign country required by Customs, for example:

"Made in (foreign country)"

(b) For the purpose of determining whether a product should be marked under paragraphs (a) (2), (3), or (4) of this section, a manufacturer needs to consider the origin of only those materials that are covered under the Act and that are one step removed from that manufacturing process. For example, a yarn manufacturer must identify fiber if it is imported, a cloth manufacturer must identify imported yarn and a household product manufacturer must identify imported cloth or imported yarn for household products made directly from yarn, or imported fiber used as filling for warmth.

(c) The term country means the political entity known as a nation. Except for the United States, colonies, possessions or protectorates outside the boundaries of the mother country shall be considered separate countries, and the name thereof shall be deemed acceptable in designating the country where the wool product was processed or manufactured unless the Commission shall otherwise direct.

(d) The country where the imported wool product was principally made shall be considered to be the country where such wool product was processed or manufactured. Further work or material added to the wool product in another country must effect a basic change in form in order to render such other country the place where such wool product was processed or manufactured.

(e) The English name of the country where the imported wool product was processed or manufactured shall be used. The adjectival form of the name of the country will be accepted as the name of the country where the wool product was processed or manufactured, provided the adjectival form of the name does not appear with such other words so as to refer to a kind of species of product. Variant spellings which clearly indicate the English name of the country, such as Brasil for Brazil and Italie for Italy, are acceptable. Abbreviations which unmistakably indicate the name of a country, such as *Gt. Britain* for *Great Britain*, are acceptable.

(f) Nothing in this Rule shall be construed as limiting in any way the

information required to be disclosed on labels under the provisions of any Tariff Act of the United States or regulations prescribed by the Secretary of the Treasury.

8. Section 300.25b is added as follows:

§ 300.25b Country of origin in mail order advertising.

When a wool product is advertised in any mail order catalog or mail order promotional material, the description of such product shall contain a clear and conspicuous statement that the product was either made in U.S.A., imported, or both. Other words or phrases with the same meaning may be used. The statement of origin required by this section shall not be inconsistent with the origin labeling of the product being advertised.

PART 303—RULES AND REGULATIONS UNDER THE TEXTILE ACT

1. In § 303.1, paragraph (u) is added as follows:

§ 303.1 Terms defined.

(u) The terms "mail order catalog" and "mail order promotional material" mean any printed materials used in the direct sale or direct offering for sale of textile products that are distributed or shown to ultimate consumers and solicit the ultimate consumers to purchase such textile products by mail, telephone or some other method without examining the actual product purchased.

2. Section 303.15 is revised to read as follows:

§ 303.15 Required label and method of affixing.

(a) A label is required to be affixed to each textile product and, where required, to its package or container in a secure manner. Such label shall be conspicuous and shall be of such durability as to remain attached to the product and its package throughout any distribution, sale, resale and until sold and delivered to the ultimate consumer.

(b) Each textile fiber product with a neck must have the label affixed to the inside center of the neck midway between the shoulder seams *provided*, however, that the required label may appear in close proximity to another label affixed to the inside center of the neck as long as the required label remains conspicuous to the consumer and, *provided further*, that if the country of origin is disclosed on a label affixed to the inside center of the neck or in close proximity, the label containing the country of origin, fiber content, and RN

or name of the company may appear in another conspicuous location on the inside or on the outside of the garment. All other textile products shall have the label affixed to a conspicuous spot on the inner side of the product or in a conspicuous place on the outside of the product.

(c) In the case of hosiery products, this section shall not be construed as requiring the affixing of a label to each hosiery product contained in a package if, (1) such hosiery products are intended for sale to the ultimate consumer in such package, (2) such package has affixed to it a label bearing the required information for the hosiery products contained in the package, and (3) the information on the label affixed to the package is equally applicable to each textile fiber product contained therein.

3. In § 303.16, paragraph (a)(3) is revised to read as follows:

§ 303.16 Arrangement and disclosure of information on labels.

(a) * * *

(3) The name of the country where such product was processed or manufactured as provided for in Rule 33.

4. Section 303.28 is revised to read as follows:

§ 303.28 Products contained in packages.

When textile products are marketed and delivered in a package which is intended to remain unbroken and intact until after delivery to the ultimate consumer, each textile product in the package, except hosiery, and the package shall be labeled with the required information. If the package is transparent to the extent it allows for a clear reading of the required information on the textile product, the package is not required to be labeled.

5. In § 303.33, paragraph (a) is revised, paragraphs (b) through (e) are redesignated (c) through (f), a new paragraph (b) is added, and newly redesignated paragraph (c) is revised to read as follows:

§ 303.33 Country where textile fiber products are processed or manufactured.

(a) In addition to the other information required by the Act and Regulations:

(1) Each imported textile fiber product shall be labeled with the name of the country where such imported product was processed or manufactured;

(2) Each textile fiber product completely made in the United States of materials that were made in the United States shall be labeled using the term "Made in U.S.A." or some other clear and equivalent term.

(3) Each textile fiber product made in the United States, either in whole or part, of imported materials shall contain a label disclosing these facts; for example:

"Made in USA of imported fabric"

or

"Knitted in USA of imported yarn" and

(4) Each textile product partially manufactured in a foreign country and partially manufactured in the United States shall contain on the label the following information:

(i) The manufacturing process in the foreign country and in the USA; for example:

"Imported cloth, finished in USA",

or

"Sewn in USA of imported components",

or

"Made in (foreign country), finished in USA"

(ii) When the U.S. Customs Service requires an origin label on the unfinished product, the manufacturing processes as required in paragraph (a)(4)(i) of this section or the name of the foreign country required by Customs, for example:

"Made in (foreign country)"

(b) For the purpose of determining whether a product should be marked under paragraphs (a) (2), (3), or (4) of this section, a manufacturer needs to consider the origin of only those materials that are covered under the Act and that are one step removed from that manufacturing process. For example, a yarn manufacturer must identify fiber if it is imported, a cloth manufacturer must identify imported yarn and a household product manufacturer must identify imported cloth or imported yarn for household products made directly from yarn, or imported fiber used as filling for warmth.

(c) The term country means the political entity known as a nation. Except for the United States, colonies, possessions or protectorates outside the boundaries of the mother country shall be considered separate countries, and the name thereof shall be deemed acceptable in designating the country where the textile fiber product was processed or manufactured unless the Commission shall otherwise direct.

6. Section 303.34 is revised to read as follows:

§ 303.34 Country of origin in mail order advertising.

When a textile fiber product is advertised in any mail order catalog or mail order promotional material, the description of such product shall contain

a clear and conspicuous statement that the product was either made in U.S.A., imported, or both. Other words or phrases with the same meaning may be used. The statement of origin required by this section shall not be inconsistent with the origin labeling of the product being advertised.

Dated: April 12, 1985.

By direction of the Commission.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 85-9262 Filed 4-15-85; 10:46 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 444 and 448

[Docket No. 80N-0012; DESI Nos. 8924 and 10826]

Oligosaccharide and Peptide Antibiotic Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations by (1) revising monographs to provide public standards for two combination anti-infective dermatological products by increasing the minimal levels of bacitracin and polymyxin B, deleting neomycin sulfate, and providing for over-the-counter use, and (2) adding new monographs to provide public standards for two additional combination dermatological products that heretofore have been released pending a final determination of effectiveness. The products were subject to the Drug Efficacy Study Implementation (DESI) program; reformulations covered by these public standards have been found to be effective.

DATES: Effective April 17, 1985; comments, notice of participation, and requests for hearing by May 17, 1985; data, information, and analyses to justify a hearing by June 17, 1985.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joan Eckert, Center for Drugs and Biologics (HFN-815), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4290.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the Federal Register, FDA is announcing the effectiveness classification and marketing conditions for a reformulation of one prescription anti-infective/corticosteroid dermatological product (DESI 10826). In another notice to be published in the near future, FDA is withdrawing approval of three prescription topical anti-infective products (DESI 8924). The three prescription products have been reformulated and will continue to be marketed for over-the-counter (OTC) use. As part of these actions, the agency is, in this final rule, amending the antibiotic drug regulations Parts 444 and 448 (21 CFR Parts 444 and 448) to provide accepted standards for these four reformulated products.

I. Three Reformulations for OTC Use

The product described in one of the new monographs in this document, § 444.5421, is a reformulation of a cream product that originally contained neomycin sulfate, polymyxin B sulfate, a gramicidin. The products described in the revisions for §§ 448.513d and 448.513e are reformulations of aerosol and powder products that originally contained neomycin sulfate, polymyxin B sulfate, and bacitracin zinc. The original formulations of these three products, marketed for prescription use, were initially classified in 1972 as possibly effective, along with other topical anti-infective products evaluated in the DESI program (37 FR 11281; June 6, 1972). The products were allowed to remain on the market while data submitted for the ongoing review of OTC drugs were evaluated.

On July 9, 1982, FDA published a notice of proposed rulemaking to establish conditions under which OTC topical first aid antibiotic drug products are generally recognized as safe and effective and not misbranded (47 FR 29986). Based on recommendations of the Advisory Review Panel on OTC Topical Antimicrobial II Drug Products and on public comments and additional data, the agency concluded that certain antibiotics can be used safely and effectively, without a prescription, as first aid to help prevent infection in minor cuts, scrapes, and burns.

In the July 9, 1982 notice, FDA specified concentrations considered acceptable for the first aid antibiotic ingredients, including neomycin sulfate, bacitracin and bacitracin zinc, and polymyxin B sulfate. The agency proposed that two or three of the listed

active ingredients may be combined provided the combination meets certain conditions. FDA also proposed labeling for such OTC "first aid antibiotics."

The products described in the new monograph § 444.5421 and in the revisions for §§ 448.513d and 448.513e meet the requirements for OTC topical first aid antibiotics that were proposed in the July 9, 1982 notice. The concentrations of the antibiotic ingredients are revised in accordance with specifications for topical antimicrobial drug products for OTC use (proposed § 333.110). Gramicidin is not included in the combination described in § 444.5421 because there is insufficient evidence for its safety and effectiveness, either alone or in combination. Neomycin sulfate is removed from the aerosol and topical powder combinations described in existing §§ 448.513d and 448.513e because of concerns about the safety of administering neomycin in these dosage forms over extensive burns or wounds, and because of the lack of evidence of their effectiveness. Approval of the previously marketed prescription formulations of these three products will be withdrawn in a future notice.

II. A Reformulation for Prescription Use

The prescription product described in the other new monograph, § 444.542k, is a reformulation of a cream product that originally contained neomycin sulfate, polymyxin B sulfate, gramicidin, and hydrocortisone. The original formulation was initially classified in the 1972 DESI notice as possibly effective (37 FR 12856; June 29, 1972). On March 28, 1984, FDA reclassified certain topical anti-infective combination drugs containing neomycin sulfate and a corticosteroid as effective for treatment of corticosteroid-responsive dermatoses (49 FR 11888). In a notice published in the Federal Register of May 4, 1984, the reclassification was extended to an ointment product containing neomycin sulfate, bacitracin zinc, polymyxin B sulfate, and hydrocortisone on the ground that the additional antibiotics broaden the antimicrobial spectrum with little, if any, increase in risk (49 FR 19147). Reformulating the combination cream product by removing gramicidin permits FDA to reclassify it as effective on the same basis as the combination ointment product. That reclassification is published elsewhere in this issue of the Federal Register.

III. Amendments to the Antibiotic Drug Regulations

The agency has determined pursuant to 21 CFR 25.24(b)(22) (proposed December 11, 1979; 44 FR 71742) that this

action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 444

Antibiotics (oligosaccharide).

21 CFR Part 448

Antibiotics (peptide).

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463, as amended (21 U.S.C. 357)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Chapter I of Title 21 of the Code of Federal Regulations is amended in Parts 444 and 448 as follows:

PART 444—OLIGOSACCHARIDE ANTIBIOTIC DRUGS

1. By adding new § 444.542k to read as follows:

§ 444.542k Neomycin sulfate-polymyxin B sulfate-hydrocortisone acetate cream.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate-polymyxin B sulfate-hydrocortisone acetate cream contains, in each gram, neomycin sulfate equivalent to 3.5 milligrams of neomycin, polymyxin B sulfate equivalent to 10,000 units of polymyxin B, and 5.0 milligrams of hydrocortisone acetate in a suitable and harmless vehicle. Its neomycin sulfate content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of milligrams of neomycin that it is represented to contain. Its polymyxin B sulfate content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of polymyxin B that it is represented to contain. The neomycin sulfate used conforms to the standards prescribed by § 444.42(a)(1). The polymyxin B sulfate used conforms to the standards prescribed by § 448.30(a)(1) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The neomycin sulfate used in making the batch for potency, loss on drying, pH, and identify.

(b) The polymyxin B sulfate used in making the batch for potency, loss on drying, pH, and identity.

(c) The batch for neomycin content and polymyxin B content.

(ii) Samples, if required by the Director, Center for Drugs and Biologics:

(a) The neomycin sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(c) The batch: A minimum of 6 immediate containers.

(b) *Tests and methods of assay:*

potency—(1) *Neomycin content.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Transfer an accurately weighed representative portion of the sample into a high-speed glass blender jar containing 1.0 milliliter polysorbate 80 and sufficient 0.1 M potassium phosphate buffer, pH 8.0 (solution 3), to obtain a stock solution of convenient concentration. Blend for 3 to 5 minutes. Dilute an aliquot of the stock solution with solution 3 to the reference concentration of 1.0 microgram of neomycin per milliliter (estimated).

(2) *Polymyxin B content.* Proceed as directed in § 436.105 of this chapter, except add to each concentration of the polymyxin B standard response line a quantity of neomycin to yield the same concentration of neomycin as that present when the sample is diluted to contain 10 units of polymyxin B per milliliter. Prepare the sample for assay as follows: Transfer an accurately weighed representative portion of the sample into a high-speed glass blender jar containing 1.0 milliliter polysorbate 80 and sufficient 10 percent potassium phosphate buffer, pH 6.0 (solution 6), to obtain a stock solution of convenient concentration. Blend for 3 to 5 minutes. Dilute an aliquot of the stock solution with solution 6 to the reference concentration of 10 units of polymyxin B per milliliter (estimated).

2. By adding new § 444.542l to read as follows:

§ 444.542l Neomycin sulfate-polymyxin B sulfate cream.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate-polymyxin B sulfate cream is a cream containing, in each gram, neomycin sulfate equivalent to 3.5 milligrams of neomycin and polymyxin B sulfate equivalent to 10,000 units of polymyxin B in a suitable and harmless vehicle. Its neomycin sulfate content is satisfactory if it is not less

than 90 percent and not more than 130 percent of the number of milligrams of neomycin that it is represented to contain. Its polymyxin B sulfate content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of polymyxin B that it is represented to contain. The neomycin sulfate used conforms to the standards prescribed by § 444.42(a)(1). The polymyxin B sulfate used conforms to the standards prescribed by § 448.30(a)(1) of this chapter.

(2) *Labeling*—(i) On the label of the immediate container and on the outside wrapper or container, if any:

(a) The batch mark;

(b) The name and quantity of each active ingredient contained in the drug; and

(c) An expiration date that conforms to the requirements prescribed by § 432.5(a)(3) of this chapter.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate directions under which the layman can use the drug safely and efficaciously.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The neomycin sulfate used in making the batch for potency, loss on drying, pH, and identity.

(b) The polymyxin B sulfate used in making the batch for potency, loss on drying, pH, and identity.

(c) The batch for neomycin content and polymyxin B content.

(ii) Samples, if required by the Director, Center for Drugs and Biologics:

(a) The neomycin sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(c) The batch: A minimum of six immediate containers.

(b) *Tests and methods of assay:*

potency—(1) *Neomycin content.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Transfer an accurately weighed representative portion of the sample into a high-speed glass blender jar containing 1.0 milliliter polysorbate 80 and sufficient 0.1 M potassium phosphate buffer, pH 8.0 (solution 3), to obtain a stock solution of convenient concentration. Blend for 3 to 5 minutes. Dilute an aliquot of the stock solution with solution 3 to the reference concentration of 1.0 microgram of neomycin per milliliter (estimated).

(2) *Polymyxin B content.* Proceed as directed in § 436.105 of this chapter, except add to each concentration of the polymyxin B standard response line a quantity of neomycin to yield the same concentration of neomycin as that present when the sample is diluted to contain 10 units of polymyxin B per milliliter. Prepare the sample for assay as follows: Transfer an accurately weighed portion of the sample into a high-speed glass blender jar containing 1.0 milliliter polysorbate 80 and sufficient 10 percent potassium phosphate buffer, pH 6.0 (solution 6), to obtain a stock solution of convenient concentration. Blend for 3 to 5 minutes. Dilute an aliquot of the stock solution with solution 6 to the reference concentration of 10 units of polymyxin B per milliliter (estimated).

PART 448—PEPTIDE ANTIBIOTIC DRUGS

1. In § 448.513d, by revising paragraphs (a) and (b)(1) to read as follows:

§ 448.513d Bacitracin zinc-polymyxin B sulfate topical powder.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Bacitracin zinc-polymyxin B sulfate topical powder contains bacitracin zinc and polymyxin B sulfate in a suitable and harmless base. Each gram contains 500 units of bacitracin and 10,000 units of polymyxin B. Its bacitracin content is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of units of bacitracin that it is represented to contain. Its polymyxin B content is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of units of polymyxin B that it is represented to contain. Its moisture content is not more than 7.0 percent. It contains not more than an average of 10 microorganisms per gram. The bacitracin zinc used conforms to the standards prescribed by § 448.13(a)(1). The polymyxin B sulfate used conforms to the standards prescribed by § 448.30(a)(1).

(2) *Labeling*—(i) On the label of the immediate container and on the outside wrapper or container, if any:

(a) The batch mark.

(b) The name and quantity of each active ingredient contained in the drug.

(c) An expiration date that conforms to the requirements prescribed by § 432.5(a)(3) of this chapter.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate

directions under which the layman can use the drug safely and efficaciously.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of test and assays on:

(a) The bacitracin zinc used in making the batch for potency, loss on drying, pH, zinc content, and identity.

(b) The polymyxin B sulfate used in making the batch for potency, loss on drying, pH, and identity.

(c) The batch for bacitracin content, polymyxin B content, moisture, and a microorganism count.

(ii) Samples, if required by the Director, Center for Drugs and Biologics:

(a) The bacitracin zinc used in making the batch: 10 packages, each containing approximately 1.0 gram.

(b) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 1.0 gram.

(c) The batch: A minimum of 12 immediate containers.

(b) *Tests and methods of assay—(1)*

Potency—(i) Bacitracin content. Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Wash an accurately weighed sample (usually 2 grams) into a 100-milliliter volumetric flask with 0.01N hydrochloric acid. Dilute to volume with 0.01N hydrochloric acid. Further dilute an aliquot with solution 1 to the reference concentration of 1.0 unit of bacitracin per milliliter (estimated).

Note.—The final sample solution must contain the same amount of hydrochloric acid as the reference concentration of the working standard.

(ii) *Polymyxin B content.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed representative portion of the sample (usually 1 gram) in 20 milliliters of sterile distilled water. Wash into an appropriate-sized volumetric flask with 10 percent potassium phosphate buffer, pH 6.0 (solution 6). Further dilute with solution 6 to the reference concentration of 10 units of polymyxin B per milliliter (estimated).

2. In § 448.513e, by revising paragraphs (a) and (b)(1) to read as follows:

§ 448.513e Bacitracin zinc-polymyxin B sulfate topical aerosol.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Bacitracin zinc-polymyxin B sulfate topical aerosol is bacitracin zinc, polymyxin B sulfate in a suitable and harmless vehicle, packaged in a

pressurized container with suitable and harmless inert gases. Each container contains 10,000 units of bacitracin and 200,000 units of polymyxin B. Its bacitracin content is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of units of bacitracin that it is represented to contain. Its polymyxin B content is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of units of polymyxin B that it is represented to contain. Its moisture content is not more than 0.5 percent. It contains not more than an average of 10 microorganisms per container. The bacitracin zinc used conforms to the standards prescribed by § 448.13(a)(1). The polymyxin B sulfate used conforms to the standards prescribed by § 448.30(a)(1) of this chapter.

(2) *Labeling—(i)* On the label of the immediate container and on the outside wrapper or container, if any:

(a) The batch mark.

(b) The name and quantity of each active ingredient contained in the drug.

(c) An expiration date that conforms to the requirements prescribed by § 432.5(a)(3) of this chapter.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate directions under which the layman can use the drug safely and efficaciously.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The bacitracin zinc used in making the batch for potency, loss on drying, pH, zinc content, and identity.

(b) The polymyxin B sulfate used in making the batch for potency, loss on drying, pH, and identity.

(c) The batch for bacitracin content, polymyxin B content, moisture, and a microorganism count.

(ii) Samples, if required by the Director, Center for Drugs and Biologics:

(a) The bacitracin zinc used in making the batch: 10 packages, each containing approximately 1.0 gram.

(b) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 1.0 gram.

(c) The batch: A minimum of 12 immediate containers.

(b) *Tests and methods of assay—(1) Potency—(i) Sample preparation.* Spray, as directed in the labeling, the entire contents of each container to be tested into a separate 2-liter Erlenmeyer flask, held in a horizontal position. Add 500 milliliters of 0.01N hydrochloric acid and shake to dissolve the contents. Immediately remove aliquots of this

sample solution and proceed as directed paragraph (b)(1)(i)(a) and (b) of this section for each antibiotic to be tested

(a) *Bacitracin content.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the sample solution with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to the reference concentration of 1.0 unit of bacitracin per milliliter (estimated).

Note.—The final sample solution must contain the same amount of hydrochloric acid as the reference concentration of the working standard.

(b) *Polymyxin B content.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the sample solution with 10 percent potassium phosphate buffer, pH 6.0 (solution 6), to the reference concentration of 10.0 units of polymyxin B per milliliter (estimated).

(ii) [Reserved]

This final rule announces standards that FDA has accepted in a request for approval of antibiotic drugs. Because this final rule is not controversial and because when effective it provides notice of accepted standards, notice and comment procedure and delayed effective date are found to be unnecessary and not in the public interest. The final rule, therefore, is effective April 17, 1985. However, interested persons may, on or before May 17, 1985, submit written comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this final rule may file objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file (1) on or before May 17, 1985, a written notice of participation and request for hearing, and (2) on or before June 17, 1985, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 430.20. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that no genuine and substantial issue of fact precludes the

action taken by this order, or if a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who request(s) the hearing, making findings and conclusions and denying a hearing. All submissions must be filed in three copies, identified with the docket number appearing in the heading of the order, and filed with the Dockets Management Branch.

The procedures and requirements governing this order, a notice of participation and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and grant or denial of a hearing are contained in 21 CFR 430.20.

All submissions under this order, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Effective date: April 17, 1985.

(Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357))

Dated: April 9, 1985.

Paul Parkman,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 85-9174 Filed 4-16-85; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 728

Medical and Dental Care for Eligible Persons at Navy Medical Department Facilities

AGENCY: Naval Medical Command, Navy, DOD.

ACTION: Final rule.

SUMMARY: The Naval Medical Command has promulgated this regulation to delineate and promulgate the policies and procedures for providing medical and dental care to eligible persons at Navy Medical Department facilities. This promulgation enumerates those persons eligible to receive medical and dental care at Navy Medical Department facilities and prescribes the extent and conditions under which medical and dental care may be provided such persons. It updates a Department of the Navy instruction for conformity with Department of Defense directives.

EFFECTIVE DATE: October 11, 1984.

ADDRESS: Commander, Naval Medical Command, Washington, DC 20372-5120.

FOR FURTHER INFORMATION CONTACT: Herbert L. Pelham, Program Analyst, Naval Medical Command, Washington, DC 20372-5120, 202-653-1179.

List of Subjects in 32 CFR Part 728

Dental health, Government employees, Health care, Military personnel.

W.M. McDermott, Jr.,

Commander, Naval Medical Command.

Accordingly, 32 CFR Part 728 is revised to read as follows:

PART 728—MEDICAL AND DENTAL CARE FOR ELIGIBLE PERSONS AT NAVY MEDICAL DEPARTMENT FACILITIES

Subpart A—General

Sec.

728.1 Mission of Navy Medical Department Facilities.

728.2 Definitions.

728.3 General Restrictions and Priorities.

728.4 Policies.

Subpart B—Members of the Uniformed Services on Active Duty

728.11 Eligible Beneficiaries.

728.12 Extent of Care.

728.13 Application for Care.

Subpart C—Members of Reserve Components, Reserve Officers' Training Corps, Navy and Marine Corps Officer Candidate Programs, and National Guard Personnel

728.21 Navy and Marine Corps Reservists.

728.22 Members of Other Reserve Components of the Uniformed Services.

728.23 Reserve Officers' Training Corps (ROTC).

728.24 Navy and Marine Corps Officer Candidate Programs.

728.25 Army and Air Force National Guard Personnel.

Subpart D—Retired Members and Dependents of the Uniformed Services

728.31 Eligible Beneficiaries.

728.32 Health Benefits Authorized.

728.33 Application for Care.

728.34 Nonavailability Statement (DD Form 1251).

728.35 Care Beyond the Capabilities of a Naval MTF.

Subpart E—Members of Foreign Military Services and Their Dependents

728.41 General Provisions.

728.42 NATO.

728.43 Members of Other Foreign Military Services and Their Dependents.

728.44 Members of Security Assistance Training Programs, Foreign Military Sales, and Their ITO Authorized Dependents.

728.45 Civilian Components (Employees of Foreign Military Services) and Their Dependents.

Subpart F—Beneficiaries of Other Federal Agencies

Sec.

728.51 General Provisions—the "Economy Act".

728.52 Veterans Administration Beneficiaries (VAB).

728.53 Department of Labor, Office of Workers' Compensation Programs (OWCP) Beneficiaries.

728.54 U.S. Public Health Services (USPHS), Other Than Members of the Uniformed Services.

728.55 Department of Justice Beneficiaries.

728.56 Treasury Department Beneficiaries.

728.57 Department of State and Associated Agencies.

728.58 Federal Aviation Administration (FAA) Beneficiaries.

728.59 Peace Corps Beneficiaries.

728.60 Job Corps and Volunteers in Service to America (VISTA) Beneficiaries.

728.61 Medicare Beneficiaries.

Subpart G—Other Persons

728.71 Ex-Service Maternity Care.

728.72 Applicants for Enrollment in the Senior Reserve Officers' Training Program.

728.73 Applicants for Enlistment or Reenlistment in the Armed Forces, and Applicants for Enlistment in the Reserve Components.

728.74 Applicants for Appointment in the Regular Navy or Marine Corps and Reserve Components, Including Members of the Reserve Components Who Apply for Active Duty.

728.75 Applicants for Cadetship at Service Academies and Applicants for the Uniformed Services University of Health Sciences (USUHS).

728.76 Naval Home Residents.

728.77 Secretarial Designees.

728.78 American Red Cross Representative and Their Dependents.

728.79 Employees of Federal Contractors and Subcontractors.

728.80 U.S. Government Employees.

728.81 Other Civilians.

728.82 Individuals Whose Military Records are Being Considered for Correction.

728.83 Persons in Military Custody and Nonmilitary Federal Prisoners.

Subpart H—Adjuncts to Medical Care

728.91 General.

728.92 Policy.

728.93 Chart of Adjuncts.

Subpart I—Reservists—Continued Treatment, Return to Limited Duty, Separation, or Retirement for Physical Disability

728.101 General.

728.102 Care From Other Than Federal Sources.

Authority: The provisions of this Part 728 issued under secs. 5031, 6011, 70A Stat. 278, 375, as amended, sec. 301, 80 Stat. 379; 5 U.S.C. 301; 10 U.S.C. 5031, 6011. Interpret or apply R.S. 4807, sec. 4, 57 Stat. 81, secs. 5537, 6148, 6201-6203, 70A Stat. 319, 383, 387, secs. 1071-1088, 72 Stat. 1445-1450, as amended; 10 U.S.C. 1071-1088, 2104, 2107, 2109, 2110, 5537, 6148, 6201-6203; 22 U.S.C. 1158, 2357, 2504.

2505, 2507, 2522; 5 U.S.C. 8101; 24 U.S.C. 15, 34, 35; 42 U.S.C. 249, 253.

Subpart A—General

§ 728.1 Mission of Navy Medical Department Facilities.

The primary mission of Navy Medical Department facilities is to provide medical and dental care for members of the Navy and Marine corps and for members of the other uniformed services who may be sick, injured, or disabled. In addition, Navy Medical Department facilities may provide medical and dental care to dependents of military personnel, to members not on active duty, and to such other persons as authorized by law, U.S. Navy regulations, and Department of Defense directives. These authorizations also provide that Navy Medical Department facilities may sometimes be called upon to furnish medical and dental care, pursuant to the laws of humanity or principles of international courtesy, to civilians and to other persons not otherwise entitled to medical and dental care.

§ 728.2 Definitions.

Unless otherwise qualified herein, the following terms when used throughout this part are defined as follows:

(a) *Active Duty*. Full-time duty in the active military service of the United States. This includes duty on the active list; full-time training duty; annual training duty; and attendance, while in the active military service, at a school designated as a service school by law or by the Secretary of the military department concerned.

(b) *Active Duty for Training*. Duty performed in the active military service by a member of the Reserve Components under orders by competent Federal authority for a specified period which provides for automatic reversion to inactive duty when the period of active duty is completed. Includes not only the period of time from reporting to the time of release but also the time of travel to and from the duty station, not in excess of the allowable constructive travel time.

(c) *CHAMPUS*. Civilian Health and Medical Program of the Uniformed Services.

(d) *Catchment Area*. The geographical area surrounding each USMTF as specified in the Military Health Services System (MHSS) Catchment Area Directory except for those portions listed in the Directory as excluded because of geographic barriers.

(e) *Chronic Condition*. Any medical or surgical condition marked by long duration or frequent recurrence—or likely to be so marked—which, in light

of medical information available, will ordinarily resist efforts to eradicate it completely; a condition which needs health benefits to achieve or maintain stability that can be provided safely only by or under the supervision of physicians, nurses, or persons authorized by physicians.

(f) *Civilian Employee*. A nonmilitary individual employed by the Federal Government and paid from nonappropriated or appropriated funds.

(g) *Cooperative Care*. Medical services and supplies for which CHAMPUS will share in the cost under circumstances specified in § 728.4(aa), even though the patient remains under the primary control of a USMTF.

(h) *Cooperative Care Coordinator*. Designated individual in a CHAMPUS contractor's office who serves as the point of contact for health benefits advisors on all matters related to supplemental-cooperative care or services provided or ordered for CHAMPUS-eligible beneficiaries by USMTF providers.

(i) *Dental Care*. Treatment which will prevent or remedy diseases, disabilities, and injuries to the teeth, jaws, and related structures and thereby contribute to maintenance or restoration of the dental health of an individual.

(j) *Dependent*. (1) *General*. When used throughout this part in reference to other than those individuals enumerated in § 728.2(j)(2), "dependent" is defined as an individual who relies for support on an individual who is eligible for services provided for in this part or qualifies for care in naval MTFs through law or some other legal agreement.

(2) *Members or Former Members, Of*. A person who bears any of the relationships in § 728.2(j) (3), (4), (5), and (6) to:

(i) An active duty or retired member of a uniformed service.

(ii) A deceased individual who, at the time of death, was an active duty or retired member of a uniformed service.

(iii) A member or former member who:

(A) Is, or was at the time of death, entitled to retired or retainer pay or equivalent pay; or

(B) Died before attaining age 60 and at the time of death:

(1) Would have been eligible for retired pay under title 10 U.S.C. 1331–1337 but for the fact that he or she was under 60 years of age, and

(2) Had elected to participate in the Survivor Benefit Plan established under title 10 U.S.C. 1447–1455, except that

(3) Such dependents as enumerated in § 728.2(j) (3), (4), (5), and (6) may not be rendered care derived from the sponsor's entitlement under title 10 U.S.C. 1331–1337 until the date on which

such members or former members would have attained age 60.

(3) *Spouse*. (i) Wife or husband regardless of whether actually dependent on the active duty or retired member.

(ii) Unremarried widow or widower, regardless of whether actually dependent on the active duty or retired member at the time of his or her death.

(4) *Child*. (i) A legitimate child, an illegitimate child of a male member whose paternity has been judicially determined, an illegitimate child of record of a female member, an adopted child, or a legitimate stepchild, who is unmarried and—

(A) Under 21 years of age regardless of whether dependent on the active duty or retired member; or

(B) Twenty-one years of age or older but incapable of self-support because of a mental or physical incapacity that existed before the 21st birthday and is, or was at the time of death of the sponsor, dependent on the sponsor for over one-half of his or her support; or

(C) Twenty-one or 22 years of age and pursuing a full-time course of education that is approved by the Secretary of Defense or Secretary of Health and Human Services (formerly HEW), as applicable, or that is approved by a State agency pursuant to chapter 32 (Post-Vietnam Era Veterans' Educational Assistance), chapter 34 (Veterans' Educational Assistance), or chapter 35 (Survivors' and Dependents' Educational Assistance) of title 38 U.S.C., for the purposes of those chapters, and is, or was at the time of death of the active duty or retired member, dependent on such member for over one-half of his or her support.

(ii) An unmarried illegitimate child (not covered in § 728.2(j)(4)(i)) or illegitimate stepchild who is, or was at the time of death of the active duty or retired member, dependent on the member or retired member for more than one-half of his or her support; residing with or in a home provided by the member parent or the parent who is the spouse of the member or retired member, and is—

(A) Under 21 years of age; or

(B) Twenty-one years of age or older but incapable of self-support because of a mental or physical incapacity that existed prior to the individual's 21st birthday; or

(C) Twenty-one or 22 years of age and pursuing a full-time course of education that is approved in accordance with § 728.2(j)(4)(i)(C).

(5) *Former Spouse*. (i) An unremarried former spouse of a member or former

member whose divorce became final on or after 1 February 1983 and who:

(A) On the date of the final decree of divorce, dissolution, or annulment had been married to the member or former member for a period of at least 20 years during which period the member or former member performed at least 20 years of service which is creditable in determining that member's or former member's eligibility for retired or former member pay, or equivalent pay, and

(B) Does not have medical coverage under an employer-sponsored health plan.

(ii) A former spouse of a deceased retired sponsor who meets the requirements of § 728.2(j)(5)(i) may be provided medical and dental care as a dependent when the sponsor:

(A) Died before attaining age 60, and

(B) At the time of his or her death would have been eligible for retired pay under chapter 67 of title 10 U.S.C. but for the fact that such sponsor was under 60 years of age.

(C) Regardless of the fact that such sponsor did not elect to participate in the Survivor Benefit Plan established under title 10 U.S.C. 1447-1455.

(6) *Parent.* Natural parent, or bona fide adoptive parent, parent-in-law, step-parent, or step-parent-in-law who is, or was at the time of death of the active duty or retired member, dependent on the member or retired member for over one-half of such parent's support and residing in a dwelling place provided or maintained by the member. (Does not include a person who stood in loco parentis.)

(k) *Designated USTFs.* The following former U.S. Public Health Service (USPHS) facilities continue to operate as "designated USTFs" for the purpose of rendering medical and dental care to active duty members and all CHAMPUS-eligible individuals.

(1) *Hospitals.* (i) Wyman Park Health Systems, 3100 Wyman Park Drive, Baltimore, MD 21211, Telephone (301) 338-3000.

(ii) Allston-Brighton Aid and Health Group, 77 Warren Street, Boston, MA 02135, Telephone (617) 782-3400.

(iii) Hospital of St. John, 2050 Space Park Drive, Nassau Bay, TX 77058, Telephone (713) 757-7430.

(iv) Seattle Public Health Hospital 1131 14th Avenue South, Seattle, WA 98144, Telephone (206) 324-7650.

(v) Bayley Seton Hospital, Bay Street and Vanderbilt Avenue, Staten Island, NY 103304, Telephone (212) 447-3010.

(2) *Clinics.* (i) Coastal Health Service, 331 Veranda, Street, Portland, ME 04103, Telephone (207) 780-3210.

(ii) Lutheran Medical Center, Downtown Health Care Services, New Post Office Bldg., W. 3rd St. & Prospect Avenue, Cleveland, OH 44113, Telephone (216) 522-4524.

(iii) St. Mary's Hospital, 440 Avenue North, Galveston, TX 77550, Telephone (713) 757-7430.

(iv) St. Joseph Ambulatory Care Center, 204 U.S. Customs Bldg., 701 San Jacinto Street, Houston, TX 77002, Telephone (713) 757-7430.

(v) Family Practice Center, Port Arthur, TX 77640, Telephone (713) 757-7430.

(l) *Disability Separation.* Temporary or permanent retirement and discharge for physical disability, with or without entitlement to receive severance pay.

(m) *Elective Care.* Medical, surgical, or dental care desired or requested by the individual or recommended by the physician or dentist which, in the opinion of other cognizant professional authority, can be performed at another place or time without jeopardizing life, limb, health, or well-being of the patient, e.g., surgery for cosmetic purposes and nonessential dental prosthetic appliances.

(n) *Emergency Care.* Medical treatment of patients with severe, life-threatening, or potentially disabling conditions that require immediate intervention to prevent undue suffering or loss of life or limb and dental treatment of painful or acute conditions.

(o) *Health Benefits Advisors (HBA).* Designated individuals at naval facilities who are responsible for advising and assisting beneficiaries covered herein concerning medical and dental benefits in uniformed services facilities and under CHAMPUS. They also provide information regarding Veterans Administration, Medicare, MEDICAID, and such other local health programs as are known to be available to beneficiaries (see § 728.4(o)).

(p) *Hospitalization.* Inpatient care in a medical treatment facility.

(q) *Inactive Duty Training (drill).* A period of training for Reserve personnel on inactive duty which includes not only that time between muster and dismissal, but also the travel to or from such drills, not in excess of the allowable constructive travel time.

(r) *Indigent.* A person who has insufficient funds or income to meet the cost of necessary medical care and services is considered to be indigent (medically).

(s) *Legitimate Care.* Those medical and dental services legally performed and not contrary to governing statutes.

(t) *Maximum Hospital Benefit.* That

point during inpatient treatment when the patient's progress appears to have stabilized and it can be anticipated that additional hospitalization will not directly contribute to any further substantial recovery. A patient who will continue to improve slowly over a long period of time without specific therapy or medical supervision, or with only a moderate amount of treatment on an outpatient basis, may be considered as having attained maximum hospital benefit.

(u) *Medical Care.* Treatment required to maintain or restore the health of an individual. Medical care may include, but is not limited to the furnishing of inpatient treatment, outpatient treatment, nursing service, medical examinations, immunizations, drugs, subsistence, transportation, and other adjuncts such as prosthetic devices, spectacles, hearing aids, orthopedic footwear, and other medically indicated appliances or services.

(v) *Medically Inappropriate.* A situation arising when denial of a Nonavailability Statement would result in significant risk to the health of a patient.

(w) *Medically Necessary.* The level of services and supplies (i.e., frequency, extent, and kinds) adequate for the diagnosis and treatment of illness or injury, including maternity care. Medically necessary includes the concept of appropriate medical care.

(x) *Medical Treatment Facility (MTF).* Any duly authorized medical department center, hospital, clinic, or other facility that provides medical, surgical, or dental care.

(y) *Member of a Uniformed Service.* A person appointed or enlisted in, or conscripted into a uniformed service.

(z) *Military Patient.* A member of a United States uniformed service on active duty, active duty for training, or inactive duty training (drill), or an active duty member of the armed forces of a foreign government who is receiving inpatient or outpatient care.

(aa) *Occupational Health Services.* Includes medical examinations and tests related to preemployment, preplacement, periodic, and pretermination; tests required for protecting the health and safety of naval personnel; job-related immunizations and chemoprophylaxis; education and training related to occupational health; and other services provided to avoid lost time or to improve effectiveness of employees. The latter shall include the

furnishing of emergency treatment of illnesses or injuries occurring at work. Such health services shall be furnished both active duty military personnel and naval civilian employees in accordance with current directives.

(bb) *Outside the United States.* All areas except the 50 States and the District of Columbia.

(cc) *Retired Member of a Uniformed Service.* A member or former member of a uniformed service who is entitled to retired or retainer pay, or equivalent pay, as a result of service in a uniformed service. This includes a member or former member who is:

- (1) Retired for length of service;
- (2) Permanently or temporarily retired for physical disability;
- (3) On the emergency officers' retired list and is entitled to retired pay for physical disability;
- (4) Otherwise in receipt of retired pay under 10 U.S.C. 1331-1337.

(dd) *Routine Care.* Medical and dental care necessary to maintain health or dental functions other than care of an emergency or elective nature.

(ee) *Supplemental Care or Services.* When medical or dental management is retained by a naval MTF and required care is not available at the facility retaining management, any additional material, professional diagnostic or consultative services, or other personal services ordered by qualified uniformed service providers, and obtained for the care of that patient are supplemental. See § 728.12 concerning the management of active duty member patients.

(ff) *Uniformed Services.* The Navy, Marine Corps, Air Force, Army, Coast Guard, Commissioned Corps of the Public Health Service, and the Commissioned Corps of the National Oceanic and Atmospheric Administration.

(gg) *United States.* The 50 States and the District of Columbia.

(hh) *USMTF.* Uniformed services medical treatment facility.

§ 728.3 General Restrictions and Priorities.

Naval MTFs shall provide care to all eligible beneficiaries subject to the capabilities of the professional staff and the availability of space and facilities. In those instances when care cannot be rendered to all eligible beneficiaries, the priorities in the following chart shall prevail. No distinction as to the sponsoring uniformed service shall be made when providing care or deciding priorities.

PRIORITIES FOR THE VARIOUS CATEGORIES OF PERSONNEL ELIGIBLE FOR CARE IN NAVY MEDICAL DEPARTMENT FACILITIES

Priority and category	Degree of entitlement
1A: Members of the uniformed services on active duty (including active duty for training and inactive duty training (drill)) and comparable personnel of the NATO nations meeting the conditions prescribed in this part.	See subpart B.
1B: Members of a Reserve Component of the Armed Forces and National Guard personnel not on active duty.	See subpart C.
2: Dependents of active duty members of the uniformed services, dependents of persons who died while in such a status, and the dependents of active duty members of NATO nations meeting the conditions prescribed in subpart E of this part.	See subparts D and E.
3: Members of the Senior Reserve Officers' Training Corps of the Armed Forces.	See § 728.23.
4: Retired members of the uniformed services and their dependents and the dependents of deceased retired members.	See subpart D.
5: Civilian employees of the Federal Government under the limited circumstances covered by the Federal Employees' Health Service Program.	See § 728.80.
6: All others, including ex-service maternity eligibles.	See subparts F and G.

§ 728.4 Policies.

(a) *Admissions to Closed Psychiatric Wards.* Patients will be admitted to closed psychiatric wards only when they have a psychiatric or emotional disorder which renders them dangerous to themselves or others, or when a period of careful closed psychiatric observation is necessary to determine whether such a condition exists. When a patient is admitted to a closed psychiatric ward, the reason for admission must be clearly stated in the patient's clinical record by the physician admitting the patient to the ward. The provisions of § 728.4(d)(3) on obtaining consent are applicable to all nonmilitary patients. These same policies apply equally in those instances when it is necessary to place a patient on an open ward under constant surveillance.

(b) *Absence From the Sick List.* See § 728.4(e), (y), and (z).

(c) *Charges and Collection.* The charges for services rendered vary and are set yearly by the Office of Management and Budget and promulgated by a yearly NAVMEDCOMNOTE 6320 (Medical, dental, subsistence rates, and hospitalization bills; cost elements of). Billing and collection actions also vary according to entitlement or eligibility and are governed by the provisions of NAVMED P-5020, Resource Management Handbook.

(d) *Consent by Nonmilitary Patients to Medical Care.* (1) Nonmilitary individuals may not be furnished medical care in any naval MTF without either their consent or the consent of a person authorized to consent on their

behalf in accordance with the provisions of applicable local laws or the order of a court having jurisdiction over the individual. Consent may be either expressed or implied. This rule applies even though an individual may be entitled by law to medical care in naval MTFs; it applies worldwide, except as it may be modified by local laws or international agreements.

(2) Implied consent is one that may be derived from actions of the patient or other circumstances, even though specific words of consent are not used. For example, a patient's application for admission to an MTF is an implied consent for hospitalization; if a patient is a minor incapable of giving consent, an implied consent of the parent may be found in actions of the parent in requesting or not objecting to medical care for the minor. Moreover, consent to treatment is implied in certain emergency situations wherein a patient is incapable of giving or denying consent, and the patient's condition represents a serious or imminent threat to life, health, or well-being.

(3) Expressed consent involves an interchange of language by which the patient, or person authorized to act on the patient's behalf, specifically states that consent is given to proposed medical care. An expressed consent may be valid whether oral or in writing, but a written consent is required (except in emergency situations as defined in § 728.4(d)(2)) and must be recorded on Standard Form 522 (Request for Administration of Anesthesia and for Performance of Operations and Other Procedures) in connection with the following when nonmilitary patients (both inpatients and outpatients) are involved:

(i) Any major or minor surgery which involves an entry into the body, either through an incision or through one of the natural body openings.

(ii) Any procedure or course of treatment in which anesthesia is used, except dental local infiltration or dental block anesthesia, whether or not an entry into the body is involved. An SF 522 is mandatory in inhalation sedation/analgesia and intravenous sedation/analgesia.

(iii) Any nonoperative procedure which involves more than a slight risk of harm to the patient, or which involves the risk of a change in the patient's body structure.

(iv) Any procedure where roentgen ray, radium, or other radioactive substance is used in the treatment of the patient.

(v) All procedures which involve electroshock or insulin coma therapy.

(vi) Admission of patients with psychotic disorders.

(vii) Admission of patients to closed wards.

(viii) All other procedures which, in the opinion of the attending physician or dentist, chief of service, commanding officer, or officer in charge, require a written consent. Any questions as to the necessity or advisability of obtaining a written consent from or on behalf of the patient should be resolved in favor of procuring such a consent.

(4) For a consent to be legally sufficient, whether implied or expressed, it must be given by a person legally capable of giving consent.

(i) The sufficiency of a consent by a nonmember minor to any medical examination or treatment will be determined by the statutory and judicial laws of the United States and the State in which the medical facility is located (e.g., many States allow the treatment of venereal disease with the consent of the minor alone and the parents need neither be informed nor their consent obtained). In instances where the consent of the minor alone is legally sufficient, the minor's decision authorizing or rejecting the proposed treatment is binding. In the absence of any law on the subject, it should be determined from the maturity of the minor involved whether he or she may give a legally sufficient consent. In these instances, particular attention shall be paid to the minor's age and level of intelligence and to the minor's understanding of the complicity and seriousness of the proposed treatment. If there is a question as to the sufficiency of the minor's consent, the advice of a judge advocate or other Government attorney should be sought. Consent of the parents will be required only when it is determined that the consent of the minor alone is not legally sufficient. Even in those circumstances where the consent of the minor is not legally sufficient, the consent of the minor patient will, nevertheless, be obtained in addition to the consent of the parents in all instances in which the minor is able to understand and fully comprehend the significance of the procedure contemplated. Further, when a situation arises in which the interest of the facility and the interest of a patient or a patient's parent or guardian are adverse, the facility may have to seek a court order empowering the facility to render the necessary care (e.g., where a parent refuses, on religious grounds, to give consent to a blood transfusion for the benefit of a minor child). Application for such a court order must be made to a Federal court pursuant to 28 U.S.C. 1345, and such court must also have

jurisdiction over the patient. Some States require a minor patient's parent or guardian to obtain court approval for procedures such as organ transplants, even though the interest of the facility and that of the patient, parent, or guardian are not adverse. Under these circumstances, it is the responsibility of the parent or guardian to obtain such an order and the court need not have jurisdiction over the facility.

(ii) If valid under the laws of the State in which the MTF is located, parents may grant powers of attorney to:

(A) Their mature minor children authorizing them to consent to medical care for themselves and other minor children of the family.

(B) Individuals standing in a temporary loco parentis status authorizing them to consent to medical care for minor children of the family.

(iii) Except in an emergency, when a patient for some reason other than mental incompetency is unable to respond, the consent of the spouse or next of kin must be obtained. If the spouse or next of kin cannot be reached, the question of authority or need to consent will be referred to the appropriate judge advocate or other Government attorney for advice.

(iv) When a judicial interpretation of mental incompetency has been made, consent must be obtained from the individual appointed by the court to act for the incompetent patient.

(v) When a question of mental incompetency arises and a judicial determination of mental incompetency has not been made, the question of authority to consent or render treatment will be referred to the appropriate judge advocate or other Government attorney for advice.

(vi) Without an appropriate court order or the consent of the patient or a person authorized to act on the patient's behalf, the commanding officer may temporarily detain a nonmilitary individual with a psychiatric disorder which makes the person dangerous to him or herself or to others, when such individual is found on the military reservation where the MTF is located. When an individual, not otherwise eligible for naval MTF services, is located off the military reservation, such temporary detention should be avoided, unless medically dictated in emergency situations (as defined in § 728.4(d)(2)) where civilian services are clearly unavailable. In such an instance, if proper consent to, or authorization for admission to the facility cannot be obtained, local civilian authorities should be notified immediately, and the individual should be transferred to those authorities. The temporary involuntary

detention of a nonmilitary individual should conform with local laws and statutes governing involuntary detention, particularly where the United States does not possess exclusive jurisdiction. To provide for situations herein discussed, arrangements should be made in advance with local civilian authorities to accept forthwith those nonmilitary psychotic individuals who may not be admitted to or retained in naval MTFs because of lack of consent or appropriate court order. In making these arrangements, the point should be made, if necessary, that such individuals who are not residents of the locality are entitled to the same care and treatment by local civilian authorities as would be transients or tourists not connected with the Federal Government.

(vii) Movement to or from a naval MTF of nonmilitary psychotic individuals without proper consent or court order normally will not be performed under the auspices of a naval MTF.

(viii) The validity of a court order directing involuntary confinement or treatment of a patient in any naval MTF is a matter for review, in each instance, by the appropriate judge advocate or other Government attorney.

(ix) When a written consent is required, it will be personally signed by the patient, or the person authorized to act on the patient's behalf.

(x) Consent for dental procedures which come under the provisions of § 728.4(d)(3)(i) and (ii) may be obtained at the time a course of treatment is started. One SF 522 may be used for a complete course of treatment.

(5) Consent Validity. One of the elements affecting the validity of a consent, whether implied or expressed, is whether the person giving consent understands that to which consent is being given and, to a sufficient degree, the possible consequences of the procedure for which consent is given. The physician or dentist who is to perform or supervise the performance of a procedure will counsel the patient or the consenting individual in a medically sound fashion as to the nature or expected results of the proposed procedure, and all known material risks peculiar to the proposed procedure, which in fact is attested to by the patient or person authorized to give consent and by the counseling physician or dentist on SF 522. This information must be provided to the patient or the person authorized to give consent on behalf of the patient in order for the consent to be informed. There are four generally recognized exceptions to this duty of the physician or dentist:

(i) Where the patient requires emergency treatment and time does not permit a discussion of the risks involved; and

(ii) Where, in the physician's or dentist's sound medical judgment (as concurred in by the commanding officer or chief of service), the risk of harm to the patient from such disclosure would far outweigh the benefits of a full informed consent.

(iii) When medical personnel are called upon to perform police-ordered procedures upon criminal suspects, medical personnel must follow State law regarding what procedures may be performed. When such a patient refuses to give consent, legal advice should be obtained before attempting to perform police-ordered procedures.

(iv) The last is a situation where consent may not be required. A so-called "therapeutic privilege" to withhold information from a patient may be recognized to exist in those situations where it is believed that full disclosure would have a detrimental effect on the patient; i.e., where it is believed that full disclosure would result in the patient being unable to make a rational decision, where disclosure would interfere or complicate continued treatment of the patient, or where disclosure would damage the patient psychologically. Even though courts have acknowledged the existence of this privilege in theory, they are reluctant to apply it to actual situations. Only in extreme cases, where the medical record sets forth fully those circumstances giving rise to the health care provider's belief that disclosure would be detrimental to the patient, is it likely that the "therapeutic privilege" would be upheld. Fear or belief that a patient might decide to forego treatment if disclosure of attendant risks were made is insufficient to trigger operation of the privilege. Judicial interpretation of the privilege has suggested that, when it is believed that disclosure would be detrimental to the patient, the only legally acceptable alternative to obtaining consent from the patient might be consent from the patient's family. Thus, while there may be a technical recognition of the "therapeutic privilege" to withhold information from the patient in certain situations, this privilege affords little or no protection for the health care provider who fails to obtain informed consent.

(e) *Convalescent Leave.* Convalescent leave, a period of authorized absence granted to active duty members under medical care when such persons are not yet fit for duty, may be granted by a member's commanding officer or the

hospital's commanding officer in accordance with the following:

(1) Unless otherwise indicated, such leave shall be granted only when recommended by COMNAVMECOM, Washington, DC, through action taken upon the report by a medical board, or the recommended findings of a physical evaluation board or higher authority.

(2) Member's commanding officer (upon advice of attending physician); commanding officers of Navy, Army, or Air Force medical facilities; commanders of regional medical commands for persons hospitalized in designated USFTs or in civilian facilities within their respective areas of authority; and managers of Veterans Administration hospitals within the 50 United States or in Puerto Rico may grant convalescent leave to active duty naval patients, with or without reference to a medical board, physical evaluation board, or higher authority provided the:

(i) Convalescent leave is being granted subsequent to a period of hospitalization.

(ii) Member is not awaiting disciplinary action of separation from the service for medical or administrative reasons.

(iii) Medical officer in charge:

(A) Considers the convalescent leave beneficial to the patient's health.

(B) Certifies that the patient is not fit for duty, will not need hospital treatment during the contemplated convalescent leave period, and that such leave will not delay final disposition of the patient.

(3) When considered necessary by the attending physician and approved on an individual basis by the commander of the respective geographic regional medical command, convalescent leave in excess of 30 days may be granted. This authority may not be redelegated to hospital commanding officers. Member's permanent command must be notified of such extensions (see MILPERSMAN 3020360).

(4) Care shall be exercised in granting convalescent leave to limit the duration of such leave to that which is essential in relation to diagnosis, prognosis, estimated duration of treatment, and probable final disposition of the patient.

(5) Upon return from convalescent leave:

(i) One copy of original orders of officers, bearing all endorsements, shall be forwarded to the Commander, Naval Military Personnel Command (COMNAV MILPERSCOM) (NMPC-4) or the Commandant of the Marine Corps (CMC), as appropriate.

(ii) An entry shall be made on the administrative remarks page (page 13

for Navy personnel) of the service records of enlisted personnel that convalescent leave was granted and showing the dates of departure and return.

(6) If considered beneficial to the patient's health, commanding officers of hospitals may grant convalescent leave as a delay in reporting back to the parent command.

(f) *Cosmetic Surgery.* (1) Defined as that surgery which is done to revise or change the texture, configuration, or relationship of contiguous structures of any feature of the human body which would be considered by the average prudent observer to be within the broad range of "normal" and acceptable variation for age or ethnic origin, and is, in addition, performed for a condition which is judged by competent medical opinion to be without potential for jeopardy to physical or mental health of an individual.

(2) Commanding officers will monitor, control, and assure compliance with the following cosmetic surgery policy:

(i) Certain cosmetic procedures are a necessary part of training and retention of skills to meet the requirements of certification and recertification.

(ii) Insofar as they meet minimum requirements and serve to improve the skills and techniques needed for reconstructive surgery, the following cosmetic procedures may be done as low priority surgery when time and space are available.

(A) Cosmetic facial rhytidectomies (face lifts) shall be part of all training programs required by certifying boards.

(B) Cosmetic augmentation mammoplasties will be done only by properly credentialed surgeons and residents within surgical training programs to meet requirements of certifying boards.

(g) *Cross-Utilization of Uniformed Services Facilities.* To provide effective cross-utilization of medical and dental facilities of the uniformed services, eligible persons, regardless of service affiliation, will be given equal opportunity for health benefits. Catchment areas (zone boundaries), designated by zip codes, have been established by the Department of Defense for each USMTF (see § 728.2(d)). Eligible beneficiaries residing within such a catchment area are expected to utilize that inpatient facility for care. EXCEPTION: Dental care, other than emergency treatment, for members of the Army and Air Force shall be provided only to those members who are either on active duty in localities where their own dental services are not available, or to those

assigned to detached duty with the Navy. Provisions shall be made to assure that:

(1) Eligible beneficiaries residing in the catchment area served by a USMTF not of the sponsor's own service may obtain care at that facility or at a facility of the sponsor's service located in another catchment area.

(2) If the facility to which an eligible beneficiary applies cannot furnish the needed care, the other facility or facilities in overlapping catchment areas will be contacted to determine whether care can be provided thereat.

(h) *Disengagement.* Applicable only to CHAMPUS-eligible individuals.

(1) Discontinuance of medical management by naval MTFs for only a specific episode of care. (Patient or sponsor should be advised to return to the naval MTF for any care required subsequent to receiving the care for which disengagement is made.) Considered accomplished only after alternative sources of care and attendant costs, if applicable, have been fully explained to patient or sponsor.

(2) Patients referred to civilian sources for total care (disengaged) under the CHAMPUS will be issued a Nonavailability Statement (DD Form 1251) in accordance with § 728.34, when appropriate. CHAMPUS-eligible patients referred for total care, who do not otherwise require a DD Form 1251 (referred for outpatient care or those referred whose residence is outside the catchment area of all USMTFs), will be given a properly completed DD Form 2161, *Referral For Civilian Medical Care*, which clearly indicates that the patient is disengaged for total care under CHAMPUS. CHAMPUS-eligible beneficiaries will be disengaged for services under CHAMPUS when:

(i) Required services are beyond the capability of the naval MTF and such services cannot be appropriately provided through one of the alternative means listed in § 728.4(aa), or

(ii) The naval MTF cannot effectively provide the required service or manage the overall course of care even if augmented by services procured from other Government or civilian sources utilizing naval MTF operation and maintenance funds as authorized in § 728.4(aa).

(i) *Domiciliary/Custodial Care.* The type of care designed essentially to assist an individual in meeting the normal activities of daily living, i.e., services which constitute personal care such as help in walking and getting in or out of bed, assistance in bathing, dressing, feeding, preparation of special diets, and supervision over medications which can usually be self-administered

and which does not entail or require the continuing attention of trained medical or paramedical personnel. The essential characteristics to be considered are the level of care and medical supervision that the patient requires, rather than such factors as diagnosis, type of condition, or the degree of functional limitation. Such care will not be provided in naval MTFs except when required for active duty members of the uniformed services.

(j) *Emergency Care.* Patients authorized only emergency care and those admitted as civilian emergencies will be treated only during the period of the emergency. Action will be initiated to effect appropriate disposition of such patients as soon as the emergency period ends.

(k) *Evaluation After Admission.* Each patient will be evaluated as soon as possible after admission and reevaluation will continue until disposition is made. Each patient's probable type and date of disposition will be anticipated and necessary processing by the various medical and administrative entities will take place concurrently with the treatment of the patient. It is especially important that the medical disposition decision be made as early as possible for U.S. military patients inasmuch as immediate transfer to a VA medical center or to a VA spinal cord injury center may be in the best interest of the patient (see BUMEDINST 8320.11D). The disposition decision for military personnel of NATO nations shall be made in conformance with § 728.42(d).

(l) *Extent of Care.* Eligible persons shall be provided medical and dental care to the extent it is authorized, required, and available. When a person is accepted for care, all care and adjuncts thereto, such as nonstandard supplies, as determined by the commanding officer to be necessary, will be provided from resources available to the commanding officer unless specifically prohibited elsewhere in this instruction. **EXCEPTION:** Hospitalization and outpatient services may be provided outside the continental limits of the United States and in Alaska to the officers and employees of any department or agency of the Federal Government, to employees of a contractor with the United States or the contractor's subcontractor, to the accompanying dependents of such persons, and in emergencies to such other persons as the Secretary of the Navy may prescribe: *provided*, that such services shall be permitted only where facilities are not otherwise available in reasonably accessible and appropriate non-Federal facilities. When a patient

has been accepted and required care is beyond the capabilities of the accepting naval MTF, the commanding officer thereof will arrange for the required care by one of the means shown below. The method of choice will be based upon professional considerations and travel economy.

(1) Transfer the patient in accordance with § 728.4(bb).

(2) Procure from civilian sources the necessary materials or professional personal services required for the proper care and treatment of the patient. Payment for the cost of such care or service depends upon the category of beneficiary being treated (see § 728.4(aa)).

(3) The care authorized in § 728.4(l)(2) will normally be accomplished in the naval MTF. However, when such action is not feasible, supplementation may be obtained elsewhere. Patients may be sent to other Federal or civilian facilities for specific treatment or services under § 728.4(l)(3) *provided* they remain under the medical management of the commanding officer of the sending facility during the entire period of care.

(m) *Family Planning Services.* Family planning services shall be provided in accordance with the provisions of SEC NAVINST 6300.2A.

(n) *Grouping of Patients.* Hospitalized patients will be grouped according to their requirements for housing and medical care, including nursing care, and will be furnished quarters, facilities, and professional supervision on that basis. Patients who must be retained under medical supervision (medical hold) solely for administrative reasons or for medical conditions which can be treated on a clinic basis will be provided quarters and messing facilities, where practicable, separately from other hospitalized patients. Medical care for such patients will be furnished on a periodic clinic appointment basis (see § 728.4(q) for handling enlisted convalescent patients). Maximum use will be made of administrative personnel in the supervision of such patients.

(o) *Health Benefits Advising.* (1) *General.* A Health Benefits Advising Program if not established must be implemented at all commands having one or more medical officers. The number of health benefits advisors (HBAs) of a command shall be commensurate with counseling and assistance requirements. The purpose of the program is to provide health benefits information and counseling to beneficiaries of the Uniformed Services Health Benefits Program (USHBP) and to others who may or may not qualify for

care in USMTFs. Office location of HBAs, their names, and telephone numbers shall be widely publicized locally. HBAs at shore establishment activities shall report workload and any changes in HBA personnel and telephone numbers on NAVMED 6320/23, Health Benefits Advisor Workload. The report (report symbol MED 6320-25) shall be submitted to the Commander, Naval Medical Command, MEDCOM-333, Washington, DC 20372 quarterly with the information for each preceding month of the quarter in its proper column. If assistance is required, contact MEDCOM-333 on Autovon 294-1127 or commercial (202) 653-1127. In addition to the duties described in § 728.4(o)(2), HBAs shall:

(i) Maintain a depository of up-to-date officially supplied information for availability to all beneficiaries.

(ii) Provide information and guidance to beneficiaries and generally support the medical and dental staff by providing assistance to eligible beneficiaries seeking or obtaining services from USMTFs, civilian facilities, VA facilities, Medicare, MEDICAID, and other health programs.

(iii) Assure that when a referral or disengagement is required:

(A) Patients are fully informed that such action is taken to provide for their immediate medical or dental requirements and has no bearing on whether care may be available in the naval MTF for other aspects of current or other future medical conditions.

(B) CHAMPUS-eligible patients are provided the services and counseling outlined in § 728.4(o)(2) prior to their departure from the facility when such beneficiaries are referred or disengaged because care required is beyond the naval MTF's capability. In an emergency, or when the patient or sponsor cannot be seen by the HBA prior to leaving, these services and counseling assistance will be accomplished as soon thereafter as possible.

(2) *Counseling and Assisting CHAMPUS-Eligible Individuals.* HBAs, as a minimum, will:

(i) Explain alternatives available to the patient.

(ii) If appropriate, explain CHAMPUS as it relates to the particular circumstance, including the cost-sharing provisions applicable to the patient, allowable charges, provider participation, and claim filing procedures. The patient or sponsor must be fully informed that when a patient is disengaged for care under CHAMPUS or when cooperative care is to be considered for payment under the provisions of § 728.4(aa) (5) and (6), the

naval MTF is not responsible for monetary amounts above the CHAMPUS-determined allowable charge or for charges CHAMPUS does not allow.

(iii) Explain why the naval MTF is paying for the supplemental care, if appropriate (see § 728.4(aa) (3) and (4)). Complete a DD Form 2161, Referral For Civilian Medical Care, marking the appropriate source of payment with the concurrence of the naval MTF commanding officer or CO's designee. Explain to the patient or sponsor how the bill will be handled.

(iv) Brief patient or sponsor on the use of the DD Form 2161 in USMTF payment procedures and CHAMPUS claims processing, as appropriate. Provide sufficient copies of DD Form 2161 and explain that CHAMPUS contractors will return claims submitted without required DD Form 2161. Obtain signature of patient or sponsor on the form.

(v) Advise patient or sponsor on arrangements for a completed copy of the DD Form 2161 to be returned to the naval MTF for payment, if appropriate, and inclusion in patient's medical record.

(vi) Arrange for counseling from appropriate sources when the patient is eligible for VA, Medicare, or MEDICAID benefits.

(vii) Serve as liaison between civilian providers and naval MTF on administrative matters related to the referral and disengagement process.

(viii) Serve as liaison between naval MTF and cooperative care coordinators on matters relating to care provided or recommended by naval MTF providers, as appropriate.

(ix) Explain why the patient is being disengaged and, in accordance with § 728.4(h)(2), provide a DD Form 1251, Nonavailability Statement, or DD Form 2161, Referral For Civilian Medical Care, as appropriate.

(p) *Immunizations.* Immunizations shall be administered in accordance with the provisions of BUMEDINST 6230.1H, unless otherwise stipulated.

(q) *Medical Holding Companies.* Medical holding companies (MHC) have been established at designated activities to facilitate handling of enlisted convalescent patients whose medical conditions are such that, although they cannot be returned to full duty, they can perform light duty ashore commensurate with their condition while completing their medical care on an outpatient basis. Where feasible, such patients shall be processed for transfer.

(r) *Notifications.* (1) *General.* The interests of the Navy, Marine Corps, and DOD have been adversely affected by

past procedures which emphasized making notifications only when an active duty member's condition was classed as either seriously ill or injured or classed as very seriously ill or injured. However, temporary disabilities which preclude communication with the next of kin have generated understandable concern and criticism, especially when emergency hospitalization has resulted. Accordingly, naval MTFs shall effect procedures to make notifications required below upon admission of the members specified. The provisions of § 728.4(r) supplement articles 1810520 and 4210100 of the Naval Military Personnel Manual and chapter 5 of Marine Corps Order P3040.4A, Marine Corps Casualty Procedures Manual; they do not supersede them.

(2) *Active Duty Flag or General Officers and Retired Marine Corps General Officers.* Message reports (Hospitalized Active Duty Flag or General Officer and Retired Marine Corps General Officer Report, MED 6320-10) shall be submitted to the Commander, Naval Medical Command, Washington, DC containing the following upon admission of subject officers:

(i) *Admission.* The initial report shall include:

(A) Officer's name, grade, social security number, and designator.

(B) Duty assignment in ship or station, or other status.

(C) Date of admission.

(D) Present condition, stating if serious or very serious.

(E) Diagnostic number only (see § 728.4(r)(2)(v)), prognosis, and estimated period of hospitalization.

(ii) *Progress Reports.* Submission frequency and content shall be at the discretion of the commanding officer. Changes in condition or status, however, shall be reported promptly.

(iii) *Termination Report.* A message shall be submitted upon termination of hospitalization which provides appropriate details for informational purposes.

(iv) *Information Addresses.* When members of the uniformed services are hospitalized, the following shall be made information addressee(s) on all messages, as appropriate:

(A) Navy—Chief of Naval Operations and Commander, Naval Military Personnel Command

(B) Marines—Chief of Naval Operations (for active duty members only) and the Commandant of the Marine Corps

(C) Army—Deputy Chief of Staff for Personnel, Department of the Army, (General Officer Management Office)

(D) Air Force—Surgeon General, United States Air Force

(v) *Privacy Act.* The right to privacy of the individual for whom hospitalization reports are made shall be safeguarded as required by the Privacy Act, implemented in the Department of the Navy by SECNAVINST 5211.5C, U.S. Navy Regulations, the Manual of the Judge Advocate General, the Marine Corps Casualty Procedures Manual, and the Manual of the Medical Department. To prevent possible invasion of privacy, the diagnosis required in § 728.4(r)(2) shall be reported only in International Classification of Diseases Annotated (ICDA) code designator.

(3) *Active Duty Members.* As part of the admission procedure, all patients shall be encouraged to communicate expeditiously and regularly with their next of kin. When a patient's incapacity makes timely personal communication impractical, i.e., fractures, burns, eye pathology, psychiatric or emotional disorders, etc., the notification process shall be initiated by MTF personnel unless the patient specifically declines such notification or where it is clear that the next of kin already has knowledge of the admission. Once notification has been made, progress reports shall be made by the facility until the patient is again able to communicate with the next of kin.

(i) *Navy Personnel.* When Navy personnel are admitted, the following notification procedures shall be effected.

(A) Outside the Contiguous 48 States and the District of Columbia. When the next of kin has accompanied the patient on the tour of duty and is in the immediate area, hospital personnel shall notify the next of kin in person, by telephone, telegraph, or by other expeditious means. If the next of kin is located in the 48 contiguous United States or the District of Columbia, telegraphic means shall be used to notify COMNAVJLPERSCOM who will provide notification to the next of kin.

(B) Within the Contiguous 48 States and the District of Columbia. Hospital personnel shall notify the next of kin in person, by telephone, telegraph, or by other expeditious means. This shall include notification of the next of kin upon arrival of all Navy patients received in the medical air-evacuation system.

(ii) *Marine Corps Personnel.* When Marine Corps personnel are admitted, the following notification procedures shall be effected.

(A) Within the Contiguous 48 States and the District of Columbia. Directors of Marine Corps districts have

responsibility for in-person notification of the next of kin of seriously ill or injured and very seriously ill or injured Marine Corps personnel. Naval MTF personnel shall assure that liaison is established with the appropriate director when such personnel are admitted. Naval MTF personnel shall notify only the appropriate Marine Corps district by telephone and request that cognizance be assumed for in-person initial notification of the next of kin of those Marine Corps patients admitted with an incapacity that makes personal and timely communication impractical and for those arriving via the medical air-evacuation system.

(B) Outside the Contiguous 48 States and the District of Columbia. Casualty notification for Marine Corps personnel hospitalized in naval MTFs outside the contiguous 48 States and the District of Columbia will be made to the Commandant of the Marine Corps (Code MSPA-1).

(C) Within and Outside the United States. The Commandant of the Marine Corps desires and encourages medical officers to communicate directly with the next of kin only after the initial in-person notification has been effected by the appropriate Marine Corps district office and notification thereof has been effected to the MTF treating the patient.

(ii) *Nonactive Duty Patients.* At the discretion of individual commanding officers, the provisions of § 728.4(r)(3) may be extended to the admission of nonactive duty patients; e.g., dependents of members on duty overseas.

(iv) *Other Uniformed Services Patients.* Liaison shall be established with other uniformed services to assure proper notification upon admission of active duty members of other services.

(4) *Messages.* (i) *Content.* Contents of message traffic (and telephonic notifications) should be phrased in lay terms and should provide sufficient details of the patient's condition, prognosis, and diagnosis. When appropriate for addressal, psychiatric and other sensitive diagnoses shall be related with discretion. When indicated, specific comment should also be included as to whether the presence of the next of kin is medically warranted.

(ii) *Information Addressee.* The Naval Medical Command requires information copies of messages only when a patient has been placed on the seriously ill or injured or the very seriously ill or injured list.

(s) *Outpatient Care.* Whenever possible, diagnostic procedures, preoperative and post operative care, surgical care, convalescence, and followup observations and treatment

will be accomplished on an outpatient basis.

(t) *Performance of Duties While In An Inpatient Status.* U.S. military patients may be assigned duties in and around naval MTFs when such duties will be, in the judgement of the attending physician, of a therapeutic value. Physical condition, past training, and other acquired skills must all be considered before assigning any patient a given task. Patients will not be assigned duties which are not within their capabilities or which require more than a very brief period of orientation.

(u) *Prolonged Definitive Medical Care.* Prolonged definitive medical care in naval MTFs will not be provided for U.S. military patients who are unlikely to return to duty. The time at which a patient should be processed for disability separation must be determined on an individual basis, taking into consideration the interest of the patient as well as those of the Government. A long-term patient roster will be maintained and updated at least once monthly to enable commanding officers and other appropriate staff members to monitor the progress of all patients with 30 or more continuous days of hospitalization. The roster will include basic patient identification data (name, grade or rate, register number, ward or absent status, clinic service, and whether assigned to a medical holding company), projected disposition (date, type, and profile), diagnosis, and cumulative hospital days (present facility and total).

(v) *Remediable Physical Defects of Active Duty Members.*

(1) *General.* When a medical evaluation reveals that a Navy or Marine Corps patient on active duty has developed a remediable defect while on active duty, the patient will be offered the opportunity of operative repair or other appropriate remediable treatment, if it is medically indicated.

(2) *Refusal of Treatment.* In accordance with MANMED art. 18-15, when a member refuses to submit to recommended therapeutic measures for a remediable defect or condition which has interfered with the member's performance of duty and following prescribed therapy, the member is expected to be fit for full duty, the following procedures shall apply:

(i) After being counseled concerning the matter, any member of the naval service who refuses to submit to recommended medical, surgical, dental, or diagnostic measures, other than routine treatment for minor or temporary disabilities, shall be transferred to a naval MTF for further

evaluation and appearance before a medical board.

(ii) The board shall study all pertinent information, inquire into the merits of the individual's refusal to submit to treatment, and report the facts with appropriate recommendations.

(iii) As a general rule, refusal of minor surgery should be considered unreasonable in the absence of substantial contraindications. Refusal of major surgical operations may be reasonable or unreasonable, according to the circumstances. The age of the patient, previous unsuccessful operations, existing physical or mental contraindications, and any special risks should all be taken into consideration.

(iv) Where surgical procedures are involved, the board's report shall contain answers to the following questions:

(A) Is surgical treatment required to relieve the incapacity and restore the individual to a duty status, and may it be expected to do so?

(B) Is the proposed surgery an established procedure that qualified and experienced surgeons ordinarily would recommend and undertake?

(C) Considering the risks ordinarily associated with surgical treatment, the patient's age and general physical condition, and the member's reason for refusing treatment, is the refusal reasonable or unreasonable? (Fear of surgery or religious scruples may be considered, along with all the other evidence, for whatever weight may appear appropriate.)

(v) If a member needing surgery is mentally competent, surgery shall not be performed over the member's protestation.

(vi) In medical, dental, or diagnostic situations, the board should show the need and risk of the recommended procedure(s).

(vii) If a medical board decides that a diagnostic, medical, dental, or surgical procedure is indicated, these findings must be made known to the patient. The board's report shall show that the patient was afforded an opportunity to submit a written statement explaining the grounds for refusal, and any statement submitted shall be forwarded with the board's report. The patient should be advised that even if the disability originally arose in line of duty, its continuance would be attributable to the member's unreasonable refusal to cooperate in its correction; and that the continuance of the disability might, therefore, result in the member's separation without benefits.

(viii) The patient shall also be advised that:

(A) Title 10 U.S.C. 1207 precludes disposition under chapter 61 of 10 U.S.C. if such a member's disability is due to intentional misconduct, willful neglect, or if it was incurred during a period of unauthorized absence.

(B) Benefits from the Veterans Administration will be dependent upon a finding that the disability was incurred in line of duty and is not due to the member's willful misconduct.

(ix) The Social Security Act contains special provisions relating to benefits for "disabled" persons and certain provisions relating to persons disabled "in line of duty" during service in the Armed Forces. In many instances persons deemed to have "remediable" disorders have been held not "disabled" within the meaning of that term as used in the statute, and Federal courts have upheld that interpretation. One who is deemed unreasonable to have refused to undergo available surgical procedures may be deemed both "not disabled" and to have incurred the condition "not in the line of duty."

(x) The board's report shall be forwarded direct to the Central Physical Evaluation Board except in those instances when the convening authority desires that the medical board report be referred for Departmental review.

(xi) In accordance with MANMED art. 18-15, a member who refuses medical, dental, or surgical treatment for a condition that existed prior to entry into the service (EPTE defect), not aggravated by a period of active service but which interferes with the performance of duties, should be processed for reason of physical disability, convenience to the Government, or enlisted in error rather than under the refusal of treatment provisions. Procedures are delineated in BUMEDINST 1910.2G and SECNAVINST 1910.4.

(3) *Other Uniformed Services Patients.* When a patient of another service is found to have a remediable physical defect developed in the military service, the matter will be referred to the nearest headquarters of the service concerned.

(w) *Responsibilities of the Commanding Officer.* In connection with the provisions of this instruction, commanding officers of naval MTFs shall:

(1) Determine which persons within the various categories authorized care in a facility will receive treatment in, be admitted to, and be discharged from that specific facility.

(2) Supervise care and treatment, including the employment of recognized professional procedures.

(3) Provide each patient with the best possible care in keeping with accepted professional standards and the assigned primary mission of the facility.

(4) Provide for counseling patients and naval MTF providers when care required is beyond the naval MTF's capability. This shall include:

(i) Establishing training programs to acquaint naval MTF providers and HBAs with the uniformed services' referral for supplemental/cooperative care or services policy outlined in § 728.4(aa).

(ii) Implementing control measures to ensure that:

(A) Providers requesting care under the provisions of § 728.4(aa) are qualified to maintain physician case management when required.

(B) Care requested under the supplemental/cooperative care criteria is medically necessary, legitimate, and otherwise permissible under the terms of that part of the USHBP under which it will be considered for payment.

(C) Providers explain to patients the reason for the referral and the type of referral being made.

(D) Attending physicians properly refer beneficiaries to the HBA for counseling and services in accordance with § 728.4(o).

(E) Uniform criteria is applied in determining cooperative care situations without consideration of rate, grade, or uniformed service affiliation.

(F) All DD Form 2161's are properly completed and approved by the commanding officer or designee.

(G) A copy of the completed DD Form 2161 is returned to the naval MTF for inclusion in the medical record of the patient.

(x) *Sick Call.* A regularly scheduled assembly of sick and injured military personnel established to provide routine medical care. Subsequent to examination, personnel medically unfit for duty will be admitted to an MTF or placed sick in quarters; personnel not admitted or placed sick in quarters shall be given such treatment as is deemed necessary. When excused from duty for medical reasons which do not require hospitalization, military personnel may be authorized to remain in quarters, not to exceed 72 hours.

(y) *Sicklist—Authorized Absence From.* Commanding officers of naval MTFs may authorize absences of up to 72 hours for dependents and retired personnel without formal discharge from the sicklist. When absences are authorized in excess of 24 hours, subsistence charges of dependent's rate, as applicable, for that period shall not be collected and the number of

reportable occupied bed days shall be appropriately reduced. Prior to authorizing such absences, the attending physician shall advise patients of their physical limitations and of any necessary safety precautions, and shall note in the clinical record that patients have been so advised. For treatment under the Medical Care Recovery Act, reporting shall be consistent with § 728.4(bb).

(z) *Subsisting Out.* A category in which officer and enlisted patients on the sicklist of a naval MTF may be placed when their daily presence is not required for treatment nor examination, but who are not yet ready for return to duty. As a general rule, patients placed in this category should reside in the area of the facility and should be examined by the attending physician at least weekly. Enlisted personnel in a subsisting out status should be granted commuted rations.

(1) Granting of subsisting out privileges is one of many disposition alternatives; however, it is recommended that other avenues (medical holding company, convalescent leave, limited duty, etc.) be considered before granting this privilege.

(2) Naval MTF patients in a subsisting out status should not be confused with those enlisted personnel in a rehabilitation program who are granted liberty and are drawing commuted rations, but are required to be present at the treating facility during normal working hours. These personnel are not subsisting out and must have a bed assigned at the naval MTF.

(3) Naval MTF patients who are required to report for examinations or treatment more often than every 48 hours should not be placed in a subsisting out status.

(aa) *Supplemental/Cooperative Care or Services.* (1) *General.* When such services as defined in § 728.2(ee) are rendered to other than CHAMPUS-eligible individuals, the cost thereof is chargeable to the operation and maintenance funds available for the operation of the facility requesting the care or services. EXCEPTION: See § 728.12 for care of active duty members. Cooperative care applies to CHAMPUS-eligible patients receiving inpatient or outpatient care in a USMTF who require care or services beyond the capability of that USMTF. The following general principles apply to such CHAMPUS-eligible patients:

(i) *Cooperation of Uniformed Services Physicians.* USMTF physicians are required to cooperate in providing CHAMPUS contractors and OCHAMPUS additional medical information. SECNAVINST 5211.5C

delineates policies, conditions, and procedures that govern safeguarding, using, accessing, and disseminating personal information kept in a system of records. Providing information to CHAMPUS contractors and OCHAMPUS shall be governed thereby.

(ii) *Physician Case Management.* Where required by BUMEDINST 6320.58 (CHAMPUS Regulation: implementation of), uniformed services physicians are required to provide case management (oversight) as would an attending or supervising civilian physician.

(iii) *CHAMPUS-Authorized Providers.* CHAMPUS contractors are responsible for determining whether a civilian provider is CHAMPUS-authorized and for providing such information, upon request, to USMTFs.

(iv) *Psychiatric/Psychotherapeutic Services.* If psychiatric care is being rendered by a psychiatric or clinical social worker, a psychiatric nurse, or a marriage and family counselor, and the uniformed services facility has made a determination that it does not have the professional staff competent to provide required physician case management, the patient may be (partially) disengaged for the psychiatric or psychotherapeutic service, yet have the remainder of required medical care provided by the naval MTF.

(v) *Forms and Documentation.* A DD Form 2161, Referral For Civilian Medical Care, will be provided to each patient who is to receive supplemental or cooperative care or services. When supplemental care is required under the provisions of § 728.4(aa)(3) and (4), the provisions of § 728.4(aa)(3)(iii) shall apply. When cooperative care or services are required under the provisions of § 728.4(aa)(5) and (6), the provisions of § 728.4(aa)(5)(iv) shall apply.

(vi) *Clarification of Unusual Circumstances.* Commanding officers of naval MTFs shall submit requests for clarification of unusual circumstance to OCHAMPUS or CHAMPUS contractors via the Commander, Naval Medical Command (MEDCOM-33) for consideration.

(2) *Care Beyond a Naval MTF's Capability.* When, either during initial evaluation or during the course of treatment of CHAMPUS-eligible beneficiaries, it is determined that required services are beyond the capability of the naval MTF, the commanding officer will arrange for the services from an alternate source in the following order, subject to restrictions specified. The provisions of § 728.4(aa)(2)(i) through (iii) must be followed before either supplemental care, authorized in § 728.4(aa)(4), is

considered for payment from Navy Operations and Maintenance funds, or cooperative care, authorized in § 728.4(aa)(6), is to be considered for payment under the terms of CHAMPUS.

(i) Obtain from another USMTF or other Federal MTF the authorized care necessary for continued treatment of the patient within the naval MTF, when such action is medically feasible and economically advantageous to the Government.

(ii) When the patient is a retired member or dependent, transfer in accordance with § 728.4(cc)(3)(i), (ii), (iii), or (iv), in that order. When the patient is a dependent of a member of a NATO nation, transfer in accordance with § 728.4(cc)(4)(i), (ii), or (iii), in that order.

(iii) With the patient's permission, the naval MTF may contact State programs, local health agencies, or health foundations to determine if benefits are available.

(iv) Obtain such supplemental care or services as delineated in § 728.4(aa)(4) from a civilian source using local operation and maintenance funds, or

(v) Obtain such cooperative care or services as delineated in § 728.4(aa)(6) from a civilian source under the terms of CHAMPUS.

(3) *Operation and Maintenance Funds.* When local operation and maintenance funds are to be used to obtain supplemental care or services, the following guidelines are applicable:

(i) Care or services must be legitimate, medically necessary, and ordered by a qualified USMTF provider.

(ii) The naval MTF must make the necessary arrangements for obtaining the required care or services from a specific source of care.

(iii) Upon approval of the naval MTF commanding officer or designee, the patient of sponsor will be provided a properly completed DD Form 2161, Referral For Civilian Medical Care. The DD Form 2161 will be marked by the health benefits advisor or other designated individual to show the naval MTF as the source of payment. Copy must also be forwarded to the MTF's contracting or supply officer who is the point of contact for coordinating obligations with the comptroller and thus the proper processing for payment.

(iv) Care on an inpatient or outpatient basis will be authorized for the minimum period necessary for the civilian provider to perform the specific test, procedure, treatment, or consultation requested. Patients receiving inpatient services in civilian medical facilities will not be counted as an occupied bed in the naval MTF, but will be continued on the MTF's inpatient

census and pay patients will continue to be charged the USMTF inpatient rate appropriate to their patient category.

(v) Naval MTF physicians will maintain professional contact with civilian providers.

(4) *Care and Services Authorized.* Referral to civilian sources for supplemental care or services, using local operation and maintenance funds, can be made for the following types of care or services:

(i) All specialty consultations for the purpose of establishing or confirming diagnoses or recommending a course of treatment.

(ii) All diagnostic tests, diagnostic examinations, and diagnostic procedures (including genetic tests and CAT scans), ordered by qualified USMTF providers.

(iii) Prescription drugs and medical supplies.

(iv) Civilian ambulance service ordered by USMTF personnel.

(5) *CHAMPUS Funds.* When payment is to be considered under the terms of CHAMPUS for cooperative care, even though the beneficiary remains under naval MTF control, the following guidelines are applicable.

(i) Charge for care will be processed under the terms of CHAMPUS.

(A) If the charge for the covered service or supply is above the CHAMPUS-determined reasonable charge, the direct care system will not assume any liability on behalf of the patient where a civilian provider is concerned, although a USMTF physician recommended or prescribed the service or supply.

(B) Payment consideration for all care or services meeting cooperative care criteria will be under the terms of CHAMPUS and payment for such care or services will not be made from naval MTF funds. Conversely, any care or services meeting naval MTF supplemental care or services payment criteria will not be considered under the terms of CHAMPUS.

(ii) Care must be legitimate and otherwise permissible under the terms of CHAMPUS and must be ordered by a qualified USMTF provider.

(iii) USMTF personnel will provide assistance to beneficiaries referred or disengaged under CHAMPUS. Although USMTF personnel are not authorized to refer beneficiaries to a specific civilian provider for care under CHAMPUS, the health benefits advisor is authorized to contact the cooperative care coordinator of the appropriate CHAMPUS contractor for assistance in determining authorized providers with the capability of providing the required services. Such information may be provided to the

beneficiary. Beneficiaries will also be encouraged to obtain required medical services only from providers willing to participate in the CHAMPUS. Subject to the availability of space, facilities, and capabilities of the staff, USMTFs will provide consultative and such other ancillary assistance as required by the civilian provider selected by the beneficiary.

(iv) Such patients who are referred (versus disengaged) to civilian sources under the terms of CHAMPUS for cooperative care will be provided a properly completed DD Form 2161. Referral For Civilian Medicare Care. The DD Form 2161 will be marked by the health benefits advisor, or other designated individual, to show CHAMPUS as the source of payment consideration. All such DD Form 2161's must be approved by the commanding officer or designee. The patient will be given sufficient copies to ensure a copy of the DD Form 2161 accompanies each CHAMPUS claim submitted for this treatment. Patients will be advised that CHAMPUS contractors will return claims received without the DD Form 2161. Also advise patients to arrange for return of a completed copy of the DD Form 2161 to the naval MTF for inclusion in their medical record.

(v) Such patients receiving inpatient or outpatient care or services will pay the patient's share of the costs as specified under the terms of CHAMPUS for their beneficiary category. Patients receiving inpatient services will not be continued on the naval MTF's census and will not be charged the USMTF inpatient rate.

(vi) Certain ancillary services authorized under CHAMPUS require physician case management during the course of treatment. USMTF physicians will manage the provision of ancillary services by civilian providers when such services are obtained under the terms of CHAMPUS. Examples include physical therapy, private duty (special) nursing, rental or lease/purchase of durable medical equipment, and services under the CHAMPUS Program for the Handicapped. USMTF providers exercising physician case management responsibility for ancillary services under CHAMPUS will be subject to the same benefit limitations and certification of need requirements applicable to civilian providers under the terms of CHAMPUS for the same types of medical care. USMTF physicians exercising physician case management responsibility will maintain professional contact with civilian providers of care.

(8) *Care and Services Authorized.* Referral to civilian sources for

cooperative care or services can be made for the following under the terms of CHAMPUS:

(i) Authorized nondiagnostic medical services such as physical therapy, speech therapy, radiation therapy, and private duty (special) nursing.

(ii) Preauthorized (by OCHAMPUS) adjunctive dental care, including orthodontia related to surgical correction of cleft palate.

(iii) Durable medical equipment. (CHAMPUS payment will be considered only if the equipment is not available on a loan basis from the naval MTF.)

(iv) Prosthetic devices (limited benefit), orthopedic braces and appliances.

(v) Optical devices (limited benefit).

(vi) Civilian ambulance service to a uniformed service facility when service is ordered by other than direct care personnel.

(vii) All care under the CHAMPUS Program for the Handicapped.

(viii) Psychotherapeutic or psychiatric care.

(ix) Except for those types of care or services delineated in § 728.4(aa)(4), all other CHAMPUS authorized medical services not available in the naval MTF (for example, neonatal intensive care).

(bb) *Third Party Liability Case.* In accordance with chapter 24, section 2403, JAG Manual, naval MTFs shall use the following guidelines to complete and submit a NAVJAG 5890/12, Hospital and Medical Care, 3rd Party Liability Case, when a third party may be liable for the injury or disease being treated:

(1) *Preparation.* The front of NAVJAG 5890/12 shall be used by all naval MTFs to report the value of medical care furnished to any patient when (i) a third party may be legally liable for causing the injury or disease, or (ii) when a Government claim is possible under workmen's compensation, no-fault insurance (see responsibilities for appraising the insurance carrier in § 728.4(bb)(5)), or under medical payments insurance (e.g., in all automobile accident cases). Block 4 of this form requires an appended statement of the patient or an accident report, if available. Prior to requesting such a statement from a patient, the person preparing the front side of NAVJAG 5890/12 shall show the patient the Privacy Act statement printed at the bottom of the form and shall have the patient sign his or her name beneath the statement.

(2) *Submission.* (i) *Naval Patients.* The completed front side of the NAVJAG 5890/12 shall be submitted to the appropriate action JAG designee listed

in section 2401 of the JAG Manual at the following times for naval patients:

(A) *Initial.* An initial submission shall be made as soon as practicable after a patient is admitted for any period of inpatient care, or if it appears that more than 7 outpatient treatments will be furnished. This submission should not be delayed pending the accumulation of all potential charges from the treating facility. This submission need not be based upon an extensive investigation of the cause of the injury or disease, but it should include all known facts. Statements by the patient, police reports, and similar information (if available), should be appended to the form.

(B) *Interim.* Interim submissions shall be made every 4 months after the initial submission until the patient is transferred or released from the facility, or changed from an inpatient status to an outpatient status.

(C) *Final.* A final submission shall be made upon completion of treatment or upon transfer of the patient to another facility. The facility to which the patient is transferred should be noted on the form. Report control symbol 5890-1 is assigned to this report.

(ii) *Nonnaval Patients.* When care is provided to personnel of another Federal agency or department, that agency or department generally will assert any claim in behalf of the United States. In such instances, the NAVJAG 5890/12's (initial, interim, and final) shall be submitted directly to the appropriate of the following addressees:

(A) *U.S. Army.* Commanding general of the Army or comparable area commander in which the incident occurred.

(B) *U.S. Air Force.* Staff judge advocate of the Air Force installation nearest the location where the initial medical care was provided.

(C) *U.S. Coast Guard.* Commandant (G-LCL/43), U.S. Coast Guard, 2100 Second Street, S.W., Washington, DC 20593.

(D) *Department of Labor.* The appropriate Office of Workers' Compensation Programs (OWCP).

(E) *Veterans Administration.* Director of the Veterans Administration hospital responsible for medical care of the injured party.

(F) *Department of Health and Human Services (DHHS).* Regional attorney's office in the area where the incident occurred.

(3) *Supplementary Documents.* An SF 502 should accompany the final submission in all cases involving inpatient care. Additionally, when Government care exceeds \$1,000, inpatient facilities should complete and

submit the back side of NAVJAG 5890/12 to the action JAG designee. On this part of the form, the determination of "patient status" may be based on local hospital usage.

(4) *Health Record Entries.* Copies of all NAVJAG 5890/12's shall be retained in the Health Record of the patient. Action JAG designees shall be notified immediately when a patient receives additional treatment subsequent to the issuance of a final NAVJAG 5890/12 if the subsequent treatment is related to the condition which gave rise to the claim.

(5) *No-Fault Insurance.* When no-fault insurance is or may be involved, the naval legal service office at which the JAG designee is located shall be responsible for apprising the insurance carrier that the Federal payment for the benefits of this instruction are secondary to any no-fault insurance coverage available to the injured individual.

(6) *Additional Guidance.* Chapter 24 of the JAG Manual and BUMEDINST 5890.1A contain supplemental information.

(cc) *Transfer of Patients.* (1) *General.* All patients will be treated at the lowest echelon equipped and staffed to provide necessary care; however, when transfer to another MTF is considered necessary, Government transportation shall be used when available. Medical regulating shall be accomplished in accordance with the provisions of OPNAVINST 4630.25B and BUMEDINST 6320.1D.

(2) *U.S. Military Patients.* U.S. military patients will not be retained in acute care MTFs longer than the minimum time necessary to attain the mental or physical state required for return to duty or separation from the service. When required care is not available at the facility providing area inpatient care, patients will be transferred to the most readily accessible USMTF or designated USMTF possessing the required capability. Transportation of the patient and a medical attendant or attendants, if required, is authorized at Government expense. The administrative procedures outlined in BUMEDINST 6320.11D shall be followed when:

(i) A patient has received the maximum benefit of hospitalization in a naval MTF but requires a protracted period of nursing home type care. The Veterans Administration can provide this type care or arrange for it from a civilian source.

(ii) It is determined that there is or may be spinal cord injury necessitating immediate medical and psychological attention. The VA is staffed and equipped to provide all necessary care in the most expeditious manner.

(iii) A determination has been made by the Secretary concerned that a member on active duty has a drug dependency or drug abuse disability.

(3) *Retired Members and Dependents.* When a retired member or a dependent requires care beyond the capabilities of a facility and a transfer is necessary, the commanding officer of that facility may:

(i) Arrange for transfer to another USMTF or designated USMTF located in an overlapping catchment area of the transferring facility if either has the required capability.

(ii) If the patient or sponsor agrees, arrange for transfer to the nearest USMTF or designated USMTF having the required capability, regardless of its location.

(iii) Arrange for transfer to the Veterans Administration MTF nearest the patient's residence if the patient is a retired member.

(iv) Provide assistance in releasing the patient to a civilian provider of the patient's choice under the terms of Medicare, if the patient is entitled. Beneficiaries entitled to Medicare, Part A, because they are 65 years of age or older or because of a disability or chronic renal disease, lose CHAMPUS eligibility but remain eligible for care in USMTFs.

(v) If the patient is authorized benefits under CHAMPUS, disengage from medical management and issue a Non-availability Statement (DD Form 1251) in accordance with the provisions of § 728.34, for care under CHAMPUS. This step should only be taken after due consideration is made of the supplemental/cooperative care policy addressed in § 728.4(aa).

(4) *Dependents of Members of NATO Nations.* When a dependent, as defined in § 728.41, of a member of a NATO nation requires care beyond the capabilities of the facility and a transfer is necessary, the commanding officer of that facility may:

(i) Arrange for transfer to another USMTF or designated USMTF having the required capability if it is located in an overlapping catchment area of the transferring facility.

(ii) If the patient or sponsor agrees, arrange for transfer to the nearest USMTF or designated USMTF having the required capability, regardless of its location.

(iii) Effect disposition in accordance with § 728.42(d).

(5) *Others.* Section 34 of title 24, United States Code, provides that hospitalization and outpatient services may be provided outside the continental limits of the United States and in Alaska to the officers and employees of any

department or agency of the Federal Government, to employees of a contractor with the United States or the contractor's subcontractor, to the dependents of such persons, and in emergencies to such other persons as the Secretary of the Navy may prescribe: *provided*, that such services shall be permitted only where facilities are not otherwise available in reasonably accessible and appropriate non-Federal facilities. In addition, the hospitalization of such persons in a naval MTF is limited by section 35 of title 24, United States Code, to the treatment of acute medical and surgical conditions, exclusive of nervous, mental, or contagious diseases, or those requiring domiciliary care. Section 35 of title 24 also limits dental care for such persons to treatment that is an adjunct to inpatient hospital care and excludes any dental prosthesis or orthodontia. The transfer and subsequent treatment of such patients shall be in accordance with the aforementioned provisions of law.

(dd) *Verification of Patient Eligibility.*

(1) *General.* Defense Enrollment Eligibility Reporting System (DEERS) eligibility verification checks shall be used in conjunction with the identification card system as a basis for determining eligibility for medical and dental care in USMTFs. For other than emergency care, patients are required to have a valid ID card in their possession and, under the circumstances described in § 728.4(dd)(1)(ii), are also required to meet certain DEERS criteria before treatment or services are rendered. Although DEERS and the ID card system are related, there may be instances where a beneficiary is in possession of an apparently valid ID card and the DEERS data base shows that eligibility has been terminated or vice versa. Consequently, eligibility indication in one system cannot override indication of ineligibility in the other without some other type of collateral documentation. Until the vast majority of eligible beneficiaries are included in the data base, dependents receiving DEERS checking shall be deemed ineligible for the reasons stated in § 728.4(dd)(3)(i) (A), (B), (C), (D), and (E).

(i) *Priorities.* With the following initial priorities, DEERS eligibility checks shall be conducted with a CRT terminal, single-digit dialer telephone, or special 800 number provided for the specific purpose of DEERS checking to:

- (A) Confirm beneficiary eligibility.
- (B) Determine whether a beneficiary is enrolled.
- (C) Identify any errors on the data base.

(ii) *Minimum Checking Requirements.* The minimum DEERS eligibility checking requirements are:

- (A) Twenty five percent of all outpatient visits.
- (B) One hundred percent of all admissions.
- (C) One hundred percent of all dental visits by nonactive duty patients to dental treatment facilities in areas designated as dentally underserved.
- (D) One hundred percent of pharmacy outpatients presenting prescriptions written by a civilian provider.

(2) *Identification Cards.* All individuals, including members of the uniformed services in uniform, shall provide valid identification when requesting health benefits, except as indicated in § 728.4(dd)(3). Although a DD Form 1173 (Uniformed Services Identification and Privilege Card) may be issued to children under 10 years of age, under normal circumstances they are not required. Accordingly, certification and identification of children under 10 years of age are the responsibility of the member or retired member, accompanying parent, legal guardian, or acting guardian. Either the DD Form 1173 issued the spouse of a member or former member or the identification card of the member or former member (DD Form 2, DD Form 2 (Ret), Form PHS-1866-1, or Form PHS-1866-3 (Ret)) is acceptable for the purpose of establishing the eligibility of a child under 10 years of age.

(i) The fact that the word "indefinite" may appear in the space for the expiration date on a member's card does not lessen its acceptability for identification of a child.

(ii) To be valid, a dependent's DD Form 1173 must have an expiration date. Should a DD Form 1173 be presented with an expiration date of "indefinite", it is invalid and shall not be honored. Furthermore, such a card shall be confiscated and forwarded to the Commander, Naval Military Personnel Command, (NMPC (641D)/Pers 7312), Department of the Navy, Washington, DC 20370 for investigation and final disposition. If emergency treatment is necessary for such a person, it shall be rendered with action and followup action initiated in accordance with the provisions of NAVMED P-5020.

(3) *Identification Procedures.* Although the most widely recognized and acceptable forms of identification are DD Form 1173, DD Form 2, Form PHS-1866-1, and Form PHS-1866-3 (Ret), individuals presenting for care without such identification may be rendered care upon presentation of other identification as outlined in this part. Under the circumstances

enumerated, the following procedures shall be followed when individuals present without the required proof of eligibility or when a DEERS check does not establish eligibility as long as a clear audit trail is maintained to support required actions and followup actions in each instance.

(i) *Minimum Requirements.* Patients presenting at USMTFs are required to be processed for DEERS eligibility verification in accordance with minimum checking requirements described in § 728.4(dd)(1)(ii). Routine nonemergency care will be denied, unless eligibility can be determined through other appropriate means (see § 728.4(dd)(3)(iii)), when a DEERS verification check is performed and eligibility cannot be verified for any of the following reasons:

- (A) Sponsor not enrolled.
- (B) Sponsor has separated from active duty and is no longer entitled to benefits.
- (C) Spouse has a final divorce decree from sponsor and not entitled to continued eligibility as a former spouse.
- (D) Dependent child is married.
- (E) Dependent becomes an active duty member of a uniformed service. (This would only apply to CHAMPUS benefits since the former dependent becomes entitled to direct care benefits in his or her own right as an active duty member.)

(ii) *Emergency Situations.* Admission or treatment shall be initiated and satisfactory collateral identification, i.e., official orders, letters, or other documentation may be accepted in lieu of an identification card or in lieu of a positive verification through a DEERS check. For dependents, collateral documentation must clearly show the relationship of the dependent to an eligible sponsor. If an emergency admission or emergency outpatient treatment is accomplished for an individual whose proof of eligibility is in question, the provisions of NAVMED P-5020 shall be initiated to minimize the write-off of uncollectible accounts. NAVMED P-5020 also specifies that followup action shall be aggressively pursued to recoup costs of care when the facility has not been reimbursed as a result of the initial action taken to collect costs due.

(iii) *Nonemergency Situations.* (A) When a prospective patient cannot present required identification and the DEERS verification process does not verify eligibility, the facility shall require the signing of a statement by the member, patient, patient's parent, legal guardian, or acting guardian attesting to the fact that eligibility has been

established in accordance with appropriate directives and stating the reason identification is not in his or her possession. Form NAVMED 6320/9, *Dependent's Eligibility for Medical Care*, shall be used to document such instances. The aforementioned responsible individual shall be apprised of the provisions on the form NAVMED 6320/9 requiring proof of eligibility within 2 working days. Persons refusing to sign the certification on the NAVMED 6320/9 shall be denied treatment or admission in nonemergency situations. If proof of eligibility is not received by the end of the second working day after treatment is rendered, action shall be taken in accordance with the provisions of NAVMED P-5020 to recoup the cost of care rendered.

(B) Possession of an ID card alone does not constitute sufficient proof of eligibility when the DEERS check does not verify eligibility. What constitutes sufficient proof will be determined by the reason the patient failed the DEERS check (see § 728.4(dd)(3)(i)). For example, the groups most expected to fail DEERS eligibility checks are members who are recent accessions and their dependents. Guard or Reserve members recently activated for training periods of 30 to 180 days and their dependents, and parents and parents-in-law with expired cards.

(1) When recent accessions are called to active duty or National Guard or Reserve Units are called to active duty for a period of 30 days or more and their dependents do not yet have DD Form 1173's, satisfactory collateral identification may be accepted in lieu thereof, i.e., official documents which establish the individual's status as a dependent of a member of a unit called to duty for a period which is not specified as 30 days or less or a telephone call to a unit orderly room or personnel office to verify that the claimed sponsor is assigned to that unit. For a child, the collateral documentation shall include satisfactory evidence that the dependent is within age limiting criteria outlined in § 728.2(j)(4). A dependent's eligibility, under the provisions of § 728.4(dd)(3)(iii)(B)(1), commences on the first day of the sponsor's active service and ceases as of midnight on the last day of active service.

(2) When parents or parents-in-law (including step-parents and step-parents-in-law) request care in naval MTFs with invalid (expired) DD Form 1173's, care shall be rendered if they or their sponsor sign a statement that an application has been submitted for a

new DD Form 1173, that the beneficiary is dependent upon the service member for over one-half of his or her support, and that there has been no material change in the beneficiary's circumstances since the previous determination of dependency and issuance of the expired card. This statement shall be placed in the beneficiary's medical record. The patient or sponsor should be informed that if eligibility is not reinstated, the facility will initiate action to recoup the cost of care. Action and followup action shall be initiated and aggressively pursued in accordance with the provisions of NAVMED P-5020.

(C) When it becomes necessary to make a determination of eligibility on other categories of individuals not covered in § 728.4(dd)(2), patient affairs personnel shall be requested to obtain a determination from the purported sponsoring agency, if appropriate. When it is necessary to treat or admit a person who is not verified as eligible by the DEERS check and cannot otherwise present proof of eligibility for care at the expense of the Government, care shall not be denied based solely on the lack of verification of eligibility through DEERS. In such instances the procedures of NAVMED P-5020 shall be followed to minimize, to the fullest extent possible, the write-off of uncollectible accounts.

(iv) *Appointments.* To prevent difficulties for the MTF, DEERS check of prospective patients with future appointments made through a central appointment desk or clinic appointment desk are necessary. Without advanced DEERS checking, patients could arrive at a clinic with an ID card but may fail the DEERS check or arrive without an ID card but is identified in the DEERS check as being eligible. Records, including the full social security number, of central appointment systems and clinic appointment systems shall be passed daily to the DEERS representative for a prospective DEERS check. This will enable appointment clerks to notify those with appointments of any apparent problem and refer them to the appropriate authority to resolve the problem prior to the appointment.

(v) *Retrospective Processing.* Medical services daily logs for walk-in patients, emergencies, or patients replacing last minute appointment cancellations shall be passed to the DEERS representative for retrospective batch processing. For DEERS processing, the last four digits of a social security number are insufficient. Accordingly, when retrospective

processing may be necessary, it is essential that the full social security number is included in the daily log for each patient.

Subpart B—Members of the Uniformed Services on Active Duty

§ 728.11 Eligible beneficiaries.

(a) A member or a uniformed service, as defined in subpart A, who is on active duty is entitled to and shall be provided medical and dental care and adjuncts thereto. For the purpose of this part, the following are also considered on active duty:

(1) Members of the National Guard in active Federal service pursuant to a "call" under 10 U.S.C. 3500 or 8500.

(2) Midshipmen of the United States Naval Academy.

(3) Cadets of the United States Military Academy.

(4) Cadets of the Air Force Academy.

(5) Cadets of the Coast Guard Academy.

(b) The following categories of personnel who are on active duty are entitled to and shall be provided medical and dental care and adjuncts thereto to the same extent as is provided for active duty members of the Regular service (except reservists when on active duty for training (ACDU TRA) as delineated in § 728.21).

(1) Members of the Reserve components.

(2) Members of the Fleet Reserve.

(3) Members of the Fleet Marine Corps Reserve.

(4) Members of the Reserve Officers' Training Corps.

(5) Members of all officer candidate programs.

(6) Retired members of the uniformed services.

§ 728.12 Extent of care.

Members who are away from their duty stations or are on duty where there is no MTF of their own service may receive care at the nearest available Federal MTF (including designated USIFs) having the capability to provide the required care. Care shall be provided without regard to whether the condition for which treatment is required was incurred or contracted in line of duty.

(a) *All Active Duty Members.* (1) All eligible beneficiaries covered in this subpart are entitled to and shall be rendered the following treatment and services upon application to a naval MTF whose mission includes the

rendering of the care required. This entitlement provides that when required care and services are beyond the capabilities of the facility to which the members applies, the commanding officer of that facility shall arrange for care from another USMTF, designated USTF, or other Federal source or may authorize and arrange for direct utilization or supplemental services and supplies from civilian non-Federal sources. The cost of services from civilian non-Federal sources shall be borne by the facility's operation and maintenance funds.

(i) Necessary hospitalization and other medical care.

(ii) Occupational health services as defined in § 728.2(aa).

(iii) Necessary prosthetic devices, prosthetic dental appliances, hearing aids, spectacles, orthopedic footwear, and other orthopedic appliances (see subpart H). When these items need repair or replacement and it is determined that the items were not damaged or lost through negligence, repair or replacement is authorized at Government expense.

(iv) Routine dental care. **EXCEPTION:** Other than emergency dental treatment for members of the Army and Air Force shall be provided only to those who are either on active duty in localities where their own dental services are not available, or to those assigned to detached duty with the Navy (MANMED art. 6-98(1)(e)).

(2) When a USMTF, with a mission of providing the care required, releases the medical management of an active duty member of the Navy, Marine Corps, Army, or Air Force, the resulting civilian health care costs will be paid by the referring facility. The member's uniformed service will be billed for care provided by the civilian facility only when the referring MTF is not organized nor authorized to provide needed health care (see 732 of this chapter for naval members). Saturation of service or facilities does not fall within this exception. When a naval MTF retains medical management, the costs of supplemental care purchased from civilian sources is paid from funds available to operate the MTF which manages care of the patient.

(b) *Maternity Episode for Active Duty Female Members.* A pregnant active duty member who lives outside the MHSS catchment area of all USMTFs is permitted to choose whether she wishes to deliver in a closer civilian hospital or travel to the USMTF for delivery. If such a member chooses to deliver in a naval MTF, makes application, and presents at that facility at the time for delivery, the provisions of § 728.12(a) apply with

respect to the furnishing of needed care, including routine newborn care (i.e., nursery, newborn examination, PKU test, etc.); arrangements for care beyond the facility's capabilities; or the expenditure of funds for supplemental care or services. Expenses incurred for the infant in USMTFs or civilian facilities (once the mother has been admitted to the USMTF) shall be paid from funds available for the care of active duty members, unless the infant becomes a patient in his or her own right either through an extension of the birthing hospital stay because of complications, subsequent transfer to another facility, or subsequent admission. If the Government is to assume financial responsibility for:

(1) Care of pregnant members residing within the MHSS catchment area of a uniformed services hospital or in the catchment area of a designated USTF, such members are required to:

(i) Make application to that facility for care, or

(ii) Obtain authorization, in accordance with part 732 of this chapter for delivery in a civilian facility.

(2) Non-Federal care of pregnant members residing outside catchment areas of USMTFs, the member must request and receive authorization in accordance with part 732 of this chapter.

(c) *Reserve and National Guard Personnel.* In addition to those services covered in § 728.12 (a) and (b), Reserve and National Guard personnel are authorized the following under conditions set forth. (See § 728.25 for additional benefits for National Guard personnel.)

(1) Personnel whose units have an active Army mission of manning missile sites are authorized spectacle inserts for protective field masks.

(2) Personnel assigned to units designated for control of civil disturbances are authorized spectacle inserts for protective field masks M17.

§ 728.13 Application for care.

Possession of an ID card (a green colored DD Form 2 (with letter suffix denoting branch of service), Armed Forces Identification Card; a green colored PHS 1866-1, Identification Card; or a red colored DD Form 2 Res (Reservists on active duty for training)) along does not constitute sufficient proof of eligibility. Accordingly, a DEERS check shall be made in accordance with § 728.4(dd) before care, other than emergency care, is rendered to the extent authorized.

Subpart C—Members of Reserve Components, Reserve Officers' Training Corps, Navy and Marine Corps Officer Candidate Program, and National Guard Personnel

§ 728.21 Navy and Marine Corps Reservists.

(a) *Scope.* This § 728.21 applies to reservists ordered to active duty for training or inactive duty training (drill) as those terms are defined in subpart A. Reservists on extended active duty shall be treated as members of the Regular service in accordance with subpart B.

(b) *Entitlement.* (1) *Reservists on Active Duty for Training (ACDUTRA).*

(i) Pursuant to 10 U.S.C. 1074(a), reservists who sustain injury, contract disease, or otherwise become ill while on active duty for training are entitled to medical and dental care to the same extent as members of the Regular service during the training period (see subpart B) subject to the provisions of § 728.21(d).

(ii) Pursuant to 10 U.S.C. 6148(a), reservists who are disabled from an injury incurred in line of duty while on active duty for training for any period of time are entitled to medical and dental care in USMTFs and designated USTFs beyond the period of training to the same extent as members of the Regular service (see subpart B) subject to the provisions of § 728.21(d).

(iii) Pursuant to 10 U.S.C. 6148(d), reservists ordered to active duty for training and reservists ordered to involuntary active duty for training for any period of time who become disabled as a result of illness or disease contracted in line of duty while so employed are entitled to medical and dental care in USMTFs beyond the period of training subject to the provisions of § 728.21(d). Such care, however, shall not extend beyond 10 weeks without either authorization from Commander, Naval Medical Command or upon approval of a medical board. When reservists require care for an extended period of time under 10 U.S.C. 6148(d), not in excess of 6 months, the provisions of subpart I are applicable.

(2) *Reservists Performing Inactive Duty Training (drill).* (i) Pursuant to 10 U.S.C. 6148(a), reservists ordered to perform inactive duty training (drill) for any period of time who are disabled in line of duty from injury sustained while so employed are entitled to medical and dental care during and beyond the training period to the same extent as members of the Regular service (see subpart B) subject to the provisions of § 728.21(d).

(ii) Pursuant to 10 U.S.C. 6148(d), reservists ordered to perform inactive duty training (drill) for any period of time who become ill or contract disease in line of duty while so employed are entitled to medical and dental care during the period of training. Beyond the training period, medical and dental care shall be provided in accordance with § 728.21(b)(1)(iii) and § 728.21(b)(2)(iii), including subpart I.

(iii) Pursuant to 10 U.S.C. 1074a, members of the uniformed services are entitled to medical and dental care for an injury incurred or aggravated while the member is traveling directly to or from a place at which the member is to perform, or has performed, inactive duty training, provided:

(A) The injury is not incurred nor aggravated as a result of the member's own gross negligence or misconduct.

(B) The care rendered is limited to that appropriate for treatment of the injury until the resulting disability cannot be materially improved by further hospitalization or treatment.

(3) *Questionable Circumstances.* In situations involving questionable circumstances, referral to the office of medical affairs or office of dental affairs is appropriate. If necessary, make referral to the Naval Medical Command (MEDCOM-33 for medical and MEDCOM-32 for dental) on determinations of entitlements.

(c) *Line of Duty.* For the purpose of this subpart C, an injury, illness, or disease which is incurred or becomes manifest while a reservist is employed in the performance of active duty for training (including authorized leave and liberty), or inactive duty training (drill), will be considered to have been incurred in line of duty (LOD) unless the condition was incurred as the result of the reservist's own misconduct or under other circumstances enumerated in JAG Manual, chapter VIII. While the LOD investigation is being conducted, such reservists remain entitled to care. If the investigation determines that the injury or illness was not incurred in line of duty, the reservist shall be charged at the civilian humanitarian nonindigent rate if further care is required in naval MTFs. While reservists on active duty for training are authorized care for all conditions which are incurred or become manifest while en route to or from such training, reservists enroute to or from inactive duty training (drill) may only be rendered care as a result of injuries. (See DOD Military Pay and Allowances Entitlement Manual for the allowable constructive travel time.)

(d) *Treatment and Services Authorized.* Reservists covered by this

subpart may be provided medical and dental care subject to the following:

(1) The following treatment or services are not authorized routinely and therefore must be approved by either the appropriate office of medical affairs or office of dental affairs, or the Commander, Naval Medical Command (MEDCOM-33 for medical and MEDCOM-32 for dental), prior to initiation of services.

(i) Conditions that existed prior to a reservist's period of training duty.

(A) Remediable physical defects.

(B) Remediable treatment for other conditions.

(C) Elective surgery.

(ii) All dental care other than emergency treatment and that treatment necessary to correct an injury incurred in the line of duty.

(2) Prosthetic devices, including dental appliances, hearing aids, spectacles, and orthopedic appliances that are lost or have become damaged during training duty, not through the negligence of the individual, may be repaired or replaced at Government expense.

(e) *Authorization for Care.* (1) Reservists covered by this subpart may be provided inpatient or outpatient care during a period of training duty without written authorization.

(2) Except in emergencies or when inpatient care initiated during a period of training duty extends beyond such period, reservists will be required to furnish written official authorization from their unit commanding officer, or higher authority, incident to receiving inpatient or outpatient care beyond the period of training duty. The letter of authorization will include name, grade or rate, social security number, and organization of the reservist; type of training duty being performed or that was being performed when the condition manifested; diagnosis (if known); and a statement that the condition was incurred in line of duty and that the reservist is entitled to care. If the reservist has been issued a notice of eligibility (NOE) (subpart I), the NOE may then be accepted in lieu of the letter of authorization. When authorization has not been obtained beforehand, care may be provided on a civilian humanitarian basis (see subpart G) pending final determination of eligibility.

§ 728.22 Members of Other Reserve Components of the Uniformed Services.

(a) Members of reserve components of the Coast Guard may be provided care the same as Navy and Marine Corps reservists.

(b) Members of reserve components of the Army and Air Force may be

provided care in naval MTFs to the same extent that they are eligible for such care in MTFs of their respective services. Consult current Army Regulation 40-3, Medical, Dental, and Veterinary Care, or Air Force Regulation 168-6, Persons Authorized Medical Care, as appropriate, for particular eligibility requirements or contact the nearest appropriate service facility.

(c) When the service directive requires written authorization, such authorization shall be obtained from the reservist's unit commanding officer or other appropriate higher authority.

(d) Naval MTFs in the United States are authorized to conduct physical examinations of and administer immunizations to inactive reserve Public Health Service commissioned officers upon presentation of a written request from the Commissioned Personnel Operations Division, OPM/OAM, 5600 Fishers Lane, Rockville, MD 20852.

§ 728.23 Reserve Officers' Training Corps (ROTC).

(a) *Eligible Beneficiaries.* (1) Members of the Senior Reserve Officers' Training Corps of the Armed Forces including students enrolled in the 4-year Senior ROTC Program or the 2-year Advanced Training Senior ROTC Program.

(2) Designated applicants for membership in the Navy, Army, and Air Force Senior ROTC Programs during their initial 8-weeks training period (practice cruises or field training).

(3) Medical, dental, pharmacy, veterinary or science allied to medicine students who are commissioned officers of a reserve component of an Armed Force who have been admitted to and training in a unit of a Senior Reserve Officers' Training Corps.

(b) *Extent of Care.* (1) While attending or en route to or from field training or practice cruises:

(i) Medical care for a condition incurred without reference to line of duty.

(ii) Routine dental care. EXCEPTION: See § 728.12(a)(4) for Army and Air Force beneficiaries.

(iii) Prosthetic devices, including dental appliances, hearing aids, spectacles, and orthopedic appliances that have become damaged or lost during training duty, not through the negligence of the individual, may be repaired or replaced as necessary as Government expense.

(iv) Care of remediable physical defects, elective surgery or other remediable treatment for conditions that existed prior to a period of training duty are not authorized without approval from the appropriate office of medical

affairs or office of dental affairs, or from the Commander, Naval Medical Command (MEDCOM-32 for medical and MEDCOM-33 for dental).

(v) Medical examinations and immunizations.

(vi) ROTC members are authorized continued medical care, including hospitalization, upon expiration of their field training or practice cruise period, in accordance with the provisions of § 728.21(b)(1) (ii) and (iii) and § 728.22.

(2) While attending a civilian educational institution:

(i) Medical care, including hospitalization, for a condition incurred in line of duty while at or traveling to or from a military installation for the purpose of undergoing medical or other examinations or for the purposes of making visits of observation, including participation in service-sponsored sports, recreational, and training activities.

(ii) Medical examinations, including hospitalization necessary for the proper conduct thereof.

(iii) Required immunizations, including hospitalization for severe reactions therefrom.

(c) *Authorization.* A letter of authorization will be prepared by the individual's commanding officer and addressed to the commanding officer of the MTF concerned.

(d) *ROTC Members as Beneficiaries of the Office of Workers' Compensation Programs (OWCP).* Under circumstances described therein, members of the ROTC shall be rendered care as outlined in § 728.53 as beneficiaries of OWCP.

§ 728.24 Navy and Marine Corps Officer Candidate Programs.

Members of the Reserve Officers Candidate Program and Platoon Leaders Class are entitled to the same medical and dental benefits as are provided members of the Navy and Marine Corps Reserve Components. Accordingly, the provisions of § 728.21 are applicable for such members. Additionally, candidates for, or persons enrolled in such programs, including members of the Women Officer's Training Class, are authorized admission to naval MTFs for the purpose of conducting special physical examination procedures which have been requested by the Commander, Naval Medical Command to determine their physical fitness for appointment to, or continuation in such a program. Upon a request from the individual's commanding officer, the officer in charge of cognizant Navy and Marine Corps recruiting stations, or officer selection officer, naval MTFs are authorized to admit such persons when,

in the opinion of the cognizant officer, hospitalization is deemed necessary for the proper conduct of the special physical examinations. Hospitalization should be kept to a minimum and treatment other than for humanitarian reasons, except as provided herein, is not authorized.

§ 728.25 Army and Air Force National Guard Personnel.

(a) *Medical Care.* Upon presentation of a letter of authorization, naval MTFs may render care as set forth in AR 40-3 (Medical, Dental, and Veterinary Care) and AFR 168-6 (Persons Authorized Medical Care) to members of the Army and Air Force National Guard who are not in a duty status. The authorizing letter shall include the name, social security number, grade, and organization of the patient; type and period of duty in which engaged (or in which engaged when the injury or illness occurred); diagnosis (if known); and will state that the injury suffered or disease contracted was in line of duty and that the individual is entitled to medical care. Entitlement determinations are a responsibility of the parent service.

(b) *Dental Care.* Dental care is limited to that adjunctive to the medical condition upon which eligibility is based and in emergencies.

(c) *Physical Examinations.* AR 40-3 and AFR 168-6 also authorize physical examinations for National Guard personnel. Accordingly, when requested by an Army or Air Force National Guard unit's commanding officer, naval MTFs may perform the requested physical examination in accordance with the appropriate service directive, subject to the availability of space, facilities, and the capabilities of the staff.

Subpart D—Retired Members and Dependents of the Uniformed Services

§ 728.31 Eligible beneficiaries.

(a) *Retired Members of the Uniformed Services.* Individuals defined in § 728.2(cc).

(b) *Dependents of.* (1) Members of the uniformed services ordered to active duty for more than 30 days.

(2) Retired members of the uniformed services, including retired and former members who are in receipt of retired pay under 10 U.S.C. 1331-1337.

(3) Members or former members who:

- Are, or were at the time of their deaths, entitled to retired or retainer pay or equivalent pay; or
- Died before attaining age 60 and at the time of their deaths:

(A) Would have been eligible for retired pay under 10 U.S.C. 1331-1337

but for the fact they were under 60 years of age, and

(B) Had elected to participate in the Survivor Benefit Plan established under 10 U.S.C. 1447-1455, except that

(1) Dependents, other than former spouses, who are otherwise eligible may not be rendered care derived from their sponsor's entitlements under 10 U.S.C. 1331-1337 until the date on which such members or former members would have attained age 60.

(2) Former spouses, eligible in accordance with § 728.2(j)(5) are entitled regardless of the fact that their sponsor did not elect to participate in the Survivor Benefit Plan established under 10 U.S.C. 1447-1455.

(4) Members of a uniformed service ordered to active duty for more than 30 days who died while on that duty.

(5) Deceased retired members.

§ 728.32 Health benefits authorized.

(a) *Retired Members.* Retired members are authorized the same medical and dental benefits as active duty members subject to the availability of space, facilities, and the capabilities of the professional staff and the priorities listed in § 728.3, except that

(1) Periodic medical examinations for members on the Temporary Disability Retired List, including hospitalization in connection with the conduct thereof, will be furnished on the same priority basis as active duty members.

(2) When vision correction is required, one pair of standard issue spectacles, or one pair of nonstandard spectacles are authorized when required to satisfy patient need. Two pairs of spectacles may be furnished only when professionally determined to be essential by the examining officer. Occupational type spectacles, such as aviation, industrial safety, double segment and mask insert, will not be furnished by military ophthalmic laboratories for retired military personnel (BUMEDINST 6810.4G).

(b) *Dependents.* Subject to the availability of space, facilities, and the capabilities of the professional staff and the priorities listed in § 728.3, dependents are authorized the following in naval MTFs:

(1) Inpatient care including services and supplies normally furnished by the MTF.

(2) Outpatient care and services.

(3) Drugs (see chapter 21, MANMED).

(i) Prescriptions written by officers of the Medical and Dental Corps, civilian physicians and dentists employed by the Navy, designated officers of the Medical Service Corps and Nurse Corps, independent duty hospital corpsmen.

and others designated to write prescriptions will be filled subject to the availability of pharmaceuticals, and consistent with control procedures and applicable laws.

(ii) Prescriptions written by civilian physicians and dentists (non-Navy employed) for eligible beneficiaries may be filled if:

(A) The commanding officer or designee determines that pharmacy personnel and funds are available.

(B) The items requested are routinely stocked.

(C) The prescribed quantity is within limitations established by the command.

(D) The prescriber is in the local area (limits designated by the commanding officer).

(E) The provisions of chapter 21, MANMED are followed when such services include the dispensing of controlled substances.

(4) Treatment on an inpatient or outpatient basis of:

(i) Medical and surgical conditions.

(ii) Contagious diseases.

(iii) Nervous, mental, and emotional disorders.

(iv) Chronic conditions and diseases.

(5) Physical examinations, including eye examinations and hearing evaluations, and all other tests and procedures necessary for a complete physical examination.

(6) Immunizations.

(7) Maternity (obstetrical) and infant care, routine care and examination of the newborn infant and well-baby care for those mothers and infants meeting the eligibility requirements of § 728.31(b). The newborn infant of an unmarried dependent minor daughter shall be classed as a civilian humanitarian nonindigent inasmuch as the infant is not a dependent of the active duty or retired service member as defined in § 728.31(b). Therefore, the minor daughter's sponsor (parent) should be counseled concerning the possibility of Secretarial designee status for the infant (see § 728.77).

(8) Diagnostic tests and services, including laboratory and x-ray examinations. Physical therapy, laboratory, x-ray, and other ambulatory diagnostic or therapeutic measures requested by non-Navy employed physicians may be provided upon approval of the commanding officer or designated department heads. The rendering of such services shall be subordinate to and shall not unduly interfere with providing inpatient and outpatient care to active duty personnel and others whose priority to receive care is equal to or greater than such dependents. The release of information to non-Navy employed physicians shall

be in consonance with applicable provision of SECNAVINST 5211.5C.

(9) Family planning services as delineated in SECNAVINST 8300.2A.

(10) Routine dental care may be provided to beneficiaries residing outside the United States. Within the United States, routine dental care may be provided only at installations which have been authorized, on an individual basis, to provide such care. At these designated installations, routine dental care may be provided only to those dependents who reside in the dentally underserved area (the MHSS catchment area of the facility), or as otherwise determined by the Secretary of the Navy. At installations within the United States not authorized to provide routine dental care, dental care is limited to:

(i) Emergency dental or oral care.

(ii) Dental care, including restorative dentistry and dental prosthetic devices, deemed necessary as an adjunct to medical or surgical treatment of a disease, condition, or injury.

(iii) Preventive measures including the fluoridation of water and the preventive dentistry program.

(iv) Consultation, examination, and diagnosis.

(11) Government ambulance services, surface or air, to transport dependents to, from, or between medical facilities when determined by the medical officer in charge to be medically necessary.

(12) Home calls when determined by the medical officer in charge to be medically necessary.

(13) Artificial limbs and artificial eyes, including initial issue, fitting, repair, replacement, and adjustment.

(14) Durable equipment such as wheelchairs, hospital beds, and resuscitators may be issued on a loan basis.

(15) Orthopedic aids, braces, crutches, elastic stockings, walking irons, and similar aids.

(16) Prosthetic devices (other than artificial limbs and eyes), hearing aids, orthopedic footwear, and spectacles or contact lenses for the correction of ordinary refractive error may not be provided dependents. These items, however, may be sold to dependents at cost to the Government outside the United States and at specific installations within the United States which have been designated by the Secretary of the Navy as remote.

(17) Special lenses (including intraocular lenses) or contact lenses for those eye conditions which require these items for complete medical or surgical management of the condition.

(18) Visa examinations for alien dependents of Armed Forces personnel at overseas locations having one or

more medical officers. Normally such examinations will consist of a superficial history and an interview to exclude present mental illness, drug addiction, psychopathic personality, or chronic alcoholism; a rather limited physical examination for overt evidence of venereal disease or leprosy; and a chest x-ray, and serology. Guidelines for examinations and procedures beyond those normally required may be found in the Manual for Examination of Aliens. This manual may be acquired from U.S. officials at American Embassies, Consular Posts, or other U.S. visa issuing offices.

§ 728.33 Application for Care.

Possession of an ID card alone (DD Form 2 (Retired), PHS-1866-3 (Retired), or DD Form 1173 (Uniformed Services Identification and Privilege Card)) does not constitute sufficient proof of eligibility. Accordingly, a DEERS check shall be instituted in accordance with § 728.4(dd) before medical and dental care may be rendered except in emergencies. When required inpatient or outpatient care is beyond the capabilities of the naval MTF, the provisions of § 728.35 shall apply. When required inpatient care cannot be rendered and the decision is made to disengage a CHAMPUS-eligible beneficiary, the provisions of § 728.34 apply.

§ 728.34 Nonavailability Statement (DD Form 1251).

(a) *General.* Pursuant to DOD Instruction 6015.19 of 15 June 1983, the following guidelines are effective as of 15 June 1983. All previously issued Nonavailability Statement guidelines and reporting requirements are superseded.

(b) *Applicability.* The following provisions are applicable to nonemergency inpatient care only. A DD Form 1251 is not required for either:

(1) Emergency care (see § 728.34(d)(1)); or

(2) When the beneficiary has other insurance paying at least 75 percent of the covered service.

(c) *Reasons for Issuance.* DD Form 1251's may be issued for only the following reasons:

(1) Proper facilities are not available.

(2) Professional capability is not available.

(3) It would be medically inappropriate (as defined in § 728.2(v)) to require the beneficiary to use the USMTF and the attending physician has specific prior approval from the facility's commanding officer or higher authority to make such determination.

(i) Issuance for this reason should be restricted to those instances when denial of the DD Form 1251 could result in a significant risk to the health of any patient requiring any clinical specialty.

(ii) Issuing authorities have discretionary authority to evaluate each situation and issue a DD Form 1251 under the "medically inappropriate" reason if:

(A) In consideration of individual medical needs, personal constraints on an individual's ability to get to the USMTF results in an unreasonable limitation on that individual's ability to get required medical care, and

(B) The issuing authority determines that obtaining care from a civilian source selected by the individual would result in significantly less limitations on that individual's ability to get required medical care than would result if the individual was required to obtain care from a USMTF.

(d) *Guidelines for Issuing.* (1) *Emergency Care.* Claims for emergency care do not require a Nonavailability Statement, however, the nature of the service or care must be certified to be an emergency by the attending physician, either on the claim form or in a separate signed and dated statement. Otherwise, CHAMPUS-eligible beneficiaries who are subject to the provisions of § 728.34 require a DD Form 1251.

(2) *Emergency Maternity Care.* Unless substantiated by medical documentation and review, a maternity admission would not be deemed as an emergency since the fact of the pregnancy would have been established well in advance of the admission. In such an instance, the beneficiary would have had sufficient opportunity to obtain a DD Form 1251 if required in her residence catchment area.

(3) *Newborn Infant(s) Remaining in Hospital After Discharge of Mother.* A newborn infant remaining in the hospital continuously after discharge of the mother does not require a separate DD Form 1251 for the first 15 days after the mother is discharged. Claims for care beyond this 15-day limitation must be accompanied by a valid DD Form 1251 issued in the infant's name. This is due to the fact that the infant becomes a patient in his or her own right (the episode of care for the infant after discharge of the mother is not considered part of the initial reason for admission of the mother (delivery), and is therefore considered a separate admission under a different diagnosis).

(4) *Beneficiary Responsibilities.* Beneficiaries are responsible for determining whether a Nonavailability Statement is required for their area of residence and for obtaining one, if

required, by first seeking nonemergency inpatient care in the USMTF serving the catchment area. Beneficiaries cannot avoid this requirement by arranging to be away from their residence when nonemergency inpatient care is obtained, e.g., staying with a relative or traveling. Individuals who require a Nonavailability Statement because they reside in the catchment area of a USMTF also require a Nonavailability Statement for nonemergency care received while away from their catchment area.

(e) *Issuing Authority.* Under the direction of the Commander, Naval Medical Command, exercised through geographic commanders of naval medical commands, naval MTFs shall issue Nonavailability Statements only when care required is not available from the naval MTF and the beneficiary's place of residence is within the catchment area (as defined in § 728.2(d)) of the issuing facility or as otherwise directed by the Secretary of Defense. When the facility's catchment area overlaps the catchment area of one or more other USMTFs with inpatient capability and the residence of the beneficiary is within the catchment area of one of more other USMTFs with inpatient capability, the issuing authority shall:

(1) Determine whether the required care is available at any of the other USMTFs whose catchment area overlaps the beneficiary's residence. Should it be available, the beneficiary shall be referred to that facility for care and a DD Form 1251 shall not be issued.

(2) Implement measures ensuring that an audit trail related to each check and referral is maintained, including the check required before retroactive issuance of a DD Form 1251 as delineated in § 728.34(g). When other than written communication is made to ascertain capability, a record shall be made in the log required in § 728.34(h) that "Telephonic (or other) determination was made on (date) that required care was not available at (name of other USMTF(s) contacted)". This notation shall be signed by the individual ascertaining this information.

(3) Once established that a DD Form 1251 is authorized and will be issued, the following shall apply:

(i) Patients shall not be referred to a specific source of care.

(ii) Nonavailability Statements issued at commands outside the United States are not valid for care received in facilities located within the United States. Statements issued within the United States are not valid for care received outside the United States.

(iii) The issuing officer shall:

(A) Prepare each DD Form 1251 in accordance with instructions on the reverse of the form. After completion, if authorized by the facility commanding officer, the issuing authority shall sign the DD Form 1251 (four-part set). Three copies shall be furnished the patient: one for the participating civilian provider, or for submission with the claim of a nonparticipating provider; one for the inpatient civilian facility; and one for retention by the sponsor or patient. The remaining copy shall be retained by the issuing facility for reporting in accordance with § 728.34(j).

(B) Explain to the patient or other responsible family member the validity period of the DD Form 1251 (see § 728.34(f)).

(C) Ensure that beneficiaries are clearly advised of the cost-sharing provisions of CHAMPUS and of the fact that the issuance of a Nonavailability Statement does not imply that CHAMPUS will allow any and all costs incurred through the use of the DD Form 1251. The issuance of a DD Form 1251 indicates only that the care requested is not available in the USMTF.

(D) Review, with the patient or responsible family member, instructions 1 through 6 on the face of the DD Form 1251 and have the patient or responsible family member sign acknowledgement that such review has been made and is understood.

(f) *Validity Period.* DD Form 1251's issued for:

(1) Other than maternity care are valid for a hospital admission occurring within 30 days of issuance and remain valid from the date of admission until 15 days after discharge from the facility rendering inpatient care. This allows for any follow-on treatment related directly to the original admission.

(2) Maternity episodes are valid if out patient or inpatient treatment related to the pregnancy is initiated within 30 days of its issuance. They remain valid for care of the mother through termination of the pregnancy and for 30 days thereafter to allow for postnatal care to be included in the maternity episode.

(g) *Retroactive Issuance.* Nonavailability Statements shall be issued retroactively only if required care could not have been rendered in a USMTF as specified in § 728.34(e) at the time services were rendered in the civilian sector. Accordingly, at the time a retroactive issuance is requested, the facility receiving the request shall determine whether capability existed at the USMTF serving the catchment area wherein the beneficiary resides (resided) or at any of the facilities in the

overlapping area described in § 728.34(e).

(h) *Annotating DD Form 1251's.* Before issuance, each DD Form 1251 shall be annotated in accordance with the instructions for completion on the reverse of each DD Form 1251. DD Form 1251's issued under the CO's discretionary authority for the "medically inappropriate" reason (§ 728.4(c)(3)(ii)) shall be annotated in the remarks section documenting the special circumstances necessitating issuance, the name and location of the source of care selected by the beneficiary, and the approximate distance from the source selected to the nearest USMTF with capability. A consecutively numbered log shall be established and maintained to include for each individual to whom a DD Form 1251 is issued:

- (1) Patient's name and identifying data.
- (2) The facility unique NAS number (item number 1 on the DD Form 1251).
- (i) *Appeals Procedures.* Beneficiaries may appeal the denial of their request for a DD Form 1251. This procedure consists of four levels within Navy, any one of which may terminate action and order issuance of a Nonavailability Statement if deemed warranted:

(1) The first level is the chief of service, or director of clinical services if the chief of service is the cognizant authority denying the beneficiary's original request.

(2) The second level is the commanding officer of the naval MTF denying the issuance. Where the appeal is denied and denial is upheld at the commanding officer's level, beneficiaries shall be informed that their appeal may be forwarded to the geographic commander having jurisdictional authority.

(3) The third level is the appropriate geographic commander. If the appeal is denied at this level, beneficiaries shall be informed that their appeal may be forwarded to the Commander, Naval Medical Command, Washington, DC.

(4) The Commander, Naval Medical Command, the fourth level of appeal, will evaluate all documentation submitted and arrive at a decision. The beneficiary will be notified in writing of this decision and the reasons therefor.

(j) *Data Collection and Reporting.* Naval MTFs with inpatient capability shall establish and maintain a system of data collection on the number of DD Form 1251's issued according to reason for issuance, clinical specialty, and the category of beneficiary to whom issued. Report this information to the Commander, Naval Medical Command (MEDCOM-31) quarterly within 15 days

after the end of the quarter, commencing with the quarter ending after the date of this instruction. When reporting the number of DD Form 1251's issued for the "medically inappropriate" reason, annotate format to provide the number included in the body of the report that were issued under the provisions of § 728.34(c)(3)(ii). Provide copies to the commander of the geographic region for information and evaluation. Inasmuch as COMNAVMECOM (MEDCOM-31) must compile and reconcile statistics from all activities, assure that information is reported only in the proper format. Modified reports received at COMNAVMECOM must be rectified causing delays in reporting to higher authority.

§ 728.35 Care Beyond the Capabilities of a Naval MTF.

When, either during initial evaluation or during the course of treatment of an individual authorized care in this subpart, it is determined that required care or services are beyond the capability of the naval MTF, the provisions of § 728.4(aa) apply.

Subpart E—Members of Foreign Military Services and Their Dependents

§ 728.41 General provisions.

(a) *Dependent.* As used in this subpart, the term "dependent" denotes a person who bears one of the following relationships to his or her sponsor:

- (1) A wife.
- (2) A husband if dependent on his sponsor for more than one-half of his support.
- (3) An unmarried legitimate child, including an adopted or stepchild who is dependent on the sponsor for over one-half of his or her support and who either:
 - (i) Has not passed the 21st birthday; or
 - (ii) Is incapable of self-support due to a physical or mental incapacity that existed prior to reaching the age of 21; or
 - (iii) Has not passed the 23rd birthday and is enrolled in a full-time course of study in an accredited institution of higher learning.

(b) *Transfer to Naval MTFs in the United States.* Personnel covered in this subpart shall not be transferred to the United States solely for the purpose of obtaining medical care at naval MTFs. Consideration may be given however, in special circumstances pursuant to the laws of humanity or principles of international courtesy. Transfer to naval MTFs in the United States of such persons located outside the United States requires approval of the

Secretary of the Navy. Naval commands, therefore, shall not commit the Navy by a promise of treatment in the United States. Approval generally will not be granted for treatment of those who suffer from incurable afflictions, who require excessive nursing or custodial care, or those who have adequate facilities in their own country. When a request is received concerning transfer for treatment at a naval MTF in the United States, the following procedures shall apply:

(1) The request shall be forwarded to the Chief of Naval Operations (OP-61), with a copy to the Commander, Naval Medical Command, Washington, DC, for administrative processing and shall include:

(i) Patient's full name and grade or rate (if dependent, the sponsor's name and grade or rate also).

(ii) Country of which a citizen.

(iii) Results of coordination with the chief of the diplomatic mission of the country involved.

(iv) Medical report giving the history, diagnosis, clinical findings, results of diagnostic tests and procedures, and all other pertinent medical information.

(v) Availability or lack thereof of professional skills and adequacy of facilities for treatment in the member's own country.

(vi) Who will assume financial responsibility for costs of hospitalization and travel.

(2) The Chief of Naval Operations (OP-61) will, if appropriate, obtain State Department clearance and guidance and advise the Secretary of the Navy accordingly. The Commander, Naval Medical Command will furnish the Chief of Naval Operations information and recommendations relative to the medical aspects and the name of the naval MTF having the capability to provide the required care. If approved, the Chief of Naval Operations will furnish, through the chain of command, the commanding officer of the designated naval MTF authorization for admission of the beneficiary for treatment.

(c) *Reimbursement.* Pub. L. 96-527 and subsequent appropriation acts contain provisions prohibiting the expenditure of appropriated funds "... to provide medical care in the United States on an inpatient basis to foreign military and diplomatic personnel or their dependents unless the Department of Defense is reimbursed for the costs of providing such care: *Provided*, that reimbursements ... shall be credited to the appropriations against which charges have been made for providing such care." Accordingly, naval MTFs in

the 50 United States shall collect full costs (full reimbursement rate (FRR)) for inpatient care provided to all foreign military personnel (not connected with a Foreign Military Sales (FMS) case number), foreign diplomatic personnel, and the dependents of both whether they are in the United States on official duty or for other reasons. (Chapter II, part 4 of NAVMED P-5020 is applicable to the collection of and accounting for such charges.)

§ 728.42 NATO.

(a) *NATO SOFA Nations.* Belgium, Canada, Denmark, Federal Republic of Germany, France, Greece, Iceland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Turkey, the United Kingdom, and the United States.

(b) *Beneficiaries.* The following personnel are beneficiaries under the conditions set forth, subject to reimbursement for inpatient care by the responsible NATO nation or individual concerned.

(1) *Members of NATO Military Services and Their Dependents.* Military personnel of NATO nations who, in connection with their official duties, are stationed in or passing through the United States, and their dependents residing in the United States with the sponsor may be provided care in naval MTFs to the same extent and under the same conditions as comparable U.S. uniformed services personnel and their dependents. Accordingly, the provisions of § 728.12 are applicable to military personnel and § 728.32(b) to accompanying dependents.

(2) *Military Ships and Aircraft Personnel.* Crew and passengers of visiting military aircraft and crews of ships of NATO nations which land or come into port at NATO or U.S. military airfields or ports within NATO countries.

(3) *NATO Liaison Officers.* In overseas areas, liaison officers from NATO Army Forces or members of a liaison detachment from such a Force.

(c) *Application for Care.* Military personnel of NATO nations stationed in the United States and their dependents shall present valid Uniformed Services Identification and Privilege Cards (DD Form 1173) when applying for care. For other eligible persons passing through the United States on official business and those enumerated in § 728.42(b) (2) and (3), orders or other official identification may be accepted in lieu of the DD Form 1173.

(d) *Disposition.* When it becomes necessary to return individuals to their home country for medical reasons, immediate notification shall be made to the NATO unit sponsoring the member

or dependent's sponsor. This notification shall include all pertinent information regarding the physical and mental condition of the individual concerned. Below are details of agreements among the Armed Forces of NATO, CENTO, and SEATO Nations on procedures for disposition of allied country patients by DOD medical installations.

(1) *Transfer of Patients.*

(i) The patient's medical welfare must be the paramount consideration. When deciding upon the transfer of a patient, due consideration should be given to any increased medical hazard which the transfer might involve.

(ii) Arrangements for disposition of patients should be capable of being implemented by existing organizations. Consequently, no new establishment should be required specially for dealing with the transferring of allied casualties.

(iii) Patients will be transferred to their own national organization at the earliest practicable opportunity consistent with the observance of principles established in § 728.42(d)(1) (i) and (ii) and under any of the following conditions:

(A) When a medical facility of their own nation is within reasonable proximity of the facility of the holding nation.

(B) When the patient is determined to require hospitalization in excess of 30 days.

(C) Where there is any question as to the ability of the patient to perform duty upon release from the MTF.

(iv) The decision as to whether a patient, other than one requiring transfer under § 728.42(d)(1)(iii), is fit for release from the MTF is the responsibility of the facility's commanding officer.

(v) All clinical documents, to include x-rays, relating to the patient will accompany such patients on transfer to their own national organization.

(vi) The decision of suitability for transfer and the arrangements for transfer will be the responsibility of the holding nation.

(vii) Final transfer channels should be arranged by local liaison before actual movement.

(viii) Patients not suitable for transfer to their own national organization must be dealt with for treatment and disposition purposes as patients of the holding nation until they are transferred, i.e., they will be dealt with in military hospitals, military medical installations, or in civilian hospitals that are part of the military medical evacuation system of the holding nation.

(2) *Classification of Patients.* Different channels for disposition will be required for the following two types of patients:

(i) *Patients Not Requiring Admission.* Patients not requiring admission to an MTF will be returned to their nearest national unit under arrangements to be made locally.

(ii) *Patients Admitted to Medical Installations.* All such patients will be dealt with in accordance with § 728.42(d)(1).

(e) *Care Authorized Outside the 48 Contiguous United States.* Major overseas commanders may authorize care in naval MTFs subject to the availability of space, facilities, and the capabilities of the professional staff in emergency situations only, provided, the required care cannot reasonably be obtained in medical facilities of the host country or in facilities of the patient's own country, or if such facilities are inadequate. Hospitalization shall be furnished only for acute medical and surgical conditions, exclusive of nervous, mental, or contagious diseases or those requiring domiciliary care. Dental treatment shall be administered only as an adjunct to authorized inpatient care and shall not include dental prostheses or orthodontia.

§ 728.43 Members of Other Foreign Military Services and Their Dependents.

(a) *Foreign Military Service Members.* For the purpose of § 728.43, members of foreign military services include only:

(1) Military personnel who are carried on the current Diplomatic List (Blue) or on the List of Employees of Diplomatic Missions (White) published by the Department of State.

(2) Military personnel assigned or attached to United States military units for duty; military personnel on foreign military supply missions accredited to and recognized by one of the military departments; and military personnel on duty in the United States at the invitation of the Secretary of Defense or one of the military departments. For the purpose of § 728.43, members of foreign Security Assistance Training Programs (SATP) and Foreign Military Sales (FMS) are not included (see § 728.44).

(3) Foreign military personnel accredited to joint United States defense boards or commissions when stationed in the United States.

(4) Foreign military personnel covered in agreements entered into by the Secretary of State, Secretary of Defense, or one of the military departments to include, but not limited to, United Nations forces personnel of foreign governments exclusive of NATO nations.

(b) *Care Authorized in the United States.* Subject to reimbursement for inpatient care as outlined in § 728.41(c).

military personnel of foreign nations not covered in § 728.42 and their dependents residing in the United States with the sponsor may be provided medical care in naval MTFs to the same extent and under the same conditions as comparable personnel of the U.S. uniformed services and their dependents, *provided*, the sponsor is in the United States in a status officially recognized by an agency of the Department of Defense. Hospitalization generally will not be granted to members or dependents who require prolonged treatment for chronic conditions, nervous or mental disorders, or domiciliary care, except in an emergency to preserve life or prevent suffering. Dental care is limited to emergencies only.

(c) *Application for Care.* All personnel covered by § 728.43 shall present orders or other official U.S. identification verifying their status when applying for care.

(d) *Disposition.* When it becomes necessary to return individuals covered by § 728.43 to their home country for medical reasons, immediate notification shall be made to the sponsoring unit of the patient or patient's sponsor with a copy to the Chief of Naval Operations (OP-61). Such notification shall include all pertinent information regarding the physical and mental condition of the individual concerned and full identification, diagnosis, prognosis, estimated period of hospitalization, and recommended disposition. Additionally, the provisions of § 728.42(d) (1) and (2) above apply.

(e) *Care Authorized Outside the 48 Contiguous United States.* Major overseas commanders may authorize care in naval MTFs subject to the availability of space, facilities, and the capabilities of the professional staff in emergency situations only, *provided*, the required care cannot reasonably be obtained in medical facilities of the host country or in facilities of the patient's own country, or if such facilities are inadequate. Hospitalization shall be furnished only for acute medical and surgical conditions, exclusive of nervous, mental, or contagious diseases or those requiring domiciliary care. Dental treatment shall be administered only as an adjunct to authorized inpatient care and shall not include dental prostheses or orthodontia.

§ 728.44 Members of Security Assistance Training Programs, Foreign Military Sales, and Their ITO Authorized Dependents.

(a) *Policies.* (1) *Invitational Travel Orders Screening.* Prior to determining the levels of care authorized or the government or person responsible for

payment for care rendered, ITOs should be carefully screened to detect variations applicable to certain foreign countries. For example, Kuwait has a civilian health plan to cover medical expenses of their trainees; trainees from the Federal Republic of Germany are personally responsible for reimbursing for inpatient care provided to their dependents; and all inpatient medical services for trainees from France and their dependents are to be borne by the individual trainee.

(2) *Elective and Definitive Surgery.* The overall policy with respect to elective and definitive surgery for Security Assistance Training Program (SATP), Foreign Military Sales (FMS) personnel and their dependents is that conservatism shall at all times prevail, except bona fide emergency situations which might threaten the life or health of an individual. Generally, elective care is not authorized nor should be commenced. However, when a commanding officer of a naval MTF considers such care necessary to the early resumption and completion of training, the complete facts shall be submitted to the Chief of Naval Operations (OP-63) for approval. Such a submission shall include the patient's name (sponsor's also if patient is an ITO (Invitational Travel Orders) authorized dependent), grade or rate, country of origin, diagnosis, type of elective care being sought, and prognosis.

(3) *Prior to Entering Training.* Upon arrival of an SATP or FMS trainee in the United States or at an overseas training site, it is discovered that the trainee cannot qualify for training by reason of a physical or mental condition which will require a significant amount of treatment before entering or completing training, such trainees shall be returned to their home country immediately or as soon thereafter as travel permits.

(4) *After Entering Training.* When trainees require hospitalization or are disabled after entering a source of training, they shall be returned to their home country as soon as practicable when, in the opinion of the commanding officer of the medical facility, hospitalization or disability will prevent training for a period in excess of 30 days. A copy of the patient's clinical records shall be forwarded with the patient. When a trainee is accepted for treatment that is not expected to exceed 30 days, the commanding officer of the training activity will be so notified. Further, when a trainee is scheduled for consecutive training sessions convening prior to the expected date of release from a naval MTF, the next scheduled training activity shall be made an information addressee. Upon release

from the MTF, the trainee shall be directed to resume training.

(b) *Care Authorized.* Generally, all SATP and FMS personnel and their ITO authorized dependents are entitled to care to the same extent. However, certain agreements require that they be charged differently and that certain exclusions apply.

(1) *NATO Members and Their ITO Authorized Dependents.*

(i) *Foreign Military Sales (FMS).* Subject to reimbursement in accordance with § 728.41(c), FMS personnel of NATO nations who are in the United States or at U.S. Armed Forces installations outside the United States and their accompanying ITO authorized dependents shall be provided medical and dental care in naval MTFs to the same extent and under the same conditions as comparable United States military personnel and their dependents except that:

(A) Dependent dental care is not authorized.

(B) Dependents are not authorized cooperative care under CHAMPUS.

(ii) *International Military Education and Training (IMET).* Subject to reimbursement for inpatient care at the appropriate IMET rate for members or at the full reimbursement rate for dependents, IMET personnel of NATO nations who are in the United States or at U.S. Armed Forces installations outside the United States and accompanying dependents shall be provided medical and dental care in naval MTFs to the same extent and under the same conditions as comparable United States military personnel and their accompanying dependents except that:

(A) Dependent dental care is not authorized.

(B) Dependents are not authorized cooperative care under CHAMPUS.

(2) *Other Foreign Members and ITO Authorized Dependents.*

(i) *Foreign Military Sales.* Subject to reimbursement for both inpatient and outpatient care at the full reimbursement rate, FMS personnel of non-NATO nations and ITO authorized accompanying dependents may be provided medical and dental care on a space available basis when facilities and staffing permit except that:

(A) Prosthetic devices, hearing aids, orthopedic footwear, and similar adjuncts are not authorized.

(B) Spectacles may be furnished when required to enable trainees to perform their assigned duties, *provided* the required spectacles are not available through civilian sources.

(C) Dental care is limited to emergency situations for the military member and is not authorized for dependents.

(D) Outpatient care is chargeable on a full reimbursable basis from either foreign military trainees or from their government. (E) Dependents are not authorized cooperative care under CHAMPUS.

(ii) *International Military Education and Training.* Subject to reimbursement for both inpatient and outpatient care at the appropriate rates for members and dependents, IMET personnel of non-NATO nations may be provided medical and dental care on a space available basis when facilities and staffing permit except that:

(A) Prosthetic devices, hearing aids, orthopedic footwear, and similar adjuncts are not authorized.

(B) Spectacles may be furnished when required to enable trainees to perform their assigned duties, *provided* the required spectacles are not available through civilian sources.

(C) Dental care is limited to emergency situations for military members and is not authorized for dependents.

(D) Dependents are not authorized cooperative care under CHAMPUS.

(c) *Application for Care.* Trainees and accompanying dependents shall present official U.S. identification or orders verifying their status when applying for care. If any doubt exists as to the extent of care authorized, ITOs should be screened (see § 728.44(a)(1)).

(d) *Notification.* When trainees require hospitalization as a result of illness or injury prior to or after entering training, the training activity (the hospital if patient has been admitted) shall make a message report through the normal chain of command to the Chief of Naval Operations (OP-63) with information copies to MAAG, COMNAVMEDCOM, Navy International Logistics Control Office (NAVILCO), Unified Commander, the affected office, and the foreign naval attaché concerned. The report shall include details of the incident, estimated period of hospitalization, physical or mental condition of the patient, and diagnosis. For further amplification, see OPNAVINST 4950.1G and NAVCOMPTRAN 032103. (Report Control Symbol OPNAV 3100-11 applies.)

§ 728.45 Civilian Components (Employees of Foreign Military Services) and Their Dependents.

(a) *Care Authorized.* Beneficiaries covered in § 728.45 are only authorized care in naval MTFs in the United States

and then only civilian humanitarian emergency care rendered at installations which have been designated as remote by the Secretary of the Navy.

Arrangements will be made to transfer such beneficiaries to a civilian facility as soon as their condition permits.

(b) *Potential Beneficiaries.* (1) *NATO.* Civilian employee personnel (and their dependents residing with them) accompanying military personnel in § 728.42(b)(1), *provided*, the beneficiaries are not stateless persons nor nationals of any state which is not a party to the North Atlantic Treaty, nor nationals of, nor ordinarily residents in the United States.

(2) *Others.* Civilian personnel not covered in § 728.45(b)(1) (and their dependents residing with them) accompanying personnel of foreign nations on duty in the United States at the invitation of the Department of Defense or one of the military departments.

(c) *Application for Care.* Personnel covered by the provisions of § 728.45 shall present orders or other official U.S. identification verifying their status when applying for care.

Subpart F—Beneficiaries of Other Federal Agencies

§ 728.51 General Provisions—the "Economy Act."

Under the provisions of 31 U.S.C. 686, any executive department or independent establishment of the Government, or any bureau thereof, if funds are available therefor and if it is determined by the head of such executive department, establishment, bureau, or office to be in the best interest of the Government so to do, may place orders with any other such department, establishment, bureau, or office for services of any kind that such requisitioned Federal agency may be in a position to supply or equipped to render. This is commonly known as the "Economy Act." Unless otherwise stipulated in this subpart F, the provisions of § 728.51 shall apply when other Federal agencies request medical or dental care for beneficiaries for whom they are responsible, including occupational health services as defined in § 728.2(aa).

§ 728.52 Veterans Administration Beneficiaries (VAB).

(a) *Eligible Beneficiaries.* Those who have served in the Armed Forces, have been separated under conditions other than dishonorable, and have been determined by the Veterans Administration (VA) to be eligible for care at VA expense.

(b) *Inpatient Control.* Each VAB admitted shall be required to conform to regulations governing the internal administration of the naval facility. Restrictive or punitive measures, including disciplinary action or denial of privileges, shall conform as nearly as possible to VA instructions.

(c) *Resolution of Problems.* All problems pertaining to VABs, including admission, medical or other records, and all correspondence shall be matters of resolution between the commanding officer of the naval facility and the VA office of jurisdiction authorizing admission. Questions of policy and administration which cannot be so resolved shall be forwarded, through the normal chain of command, to the Administrator of Veterans Affairs via COMNAVMEDCOM for resolution.

(d) *Care in the United States.* (1) *Inpatient Care.* An eligible VAB may be admitted to a naval MTF on presentation of a written authorization for admission signed by an official of the VA office of jurisdiction. Neurological and certain neuropsychiatric patients without obvious evidence of psychosis and not requiring restraints, and instances of suspected tuberculosis may be admitted for diagnosis. When diagnosed, instances of psychosis, psychoneurosis, and tuberculosis of present clinical significance shall be reported promptly to the VA office of jurisdiction with a request for transfer to a VA facility.

(i) *Extent of Care.* Eligible VABs shall be furnished medical and surgical care, including prostheses such as eyes and limbs, and appliances such as hearing aids, spectacles, or orthopedic appliances when required for the proper treatment of the condition upon which eligibility is based.

(ii) *Disposition of Emergency Admissions.* Commanding officers of naval MTFs shall notify the appropriate VA office of jurisdiction by message or other expeditious means within 72 hours after the date and hour of an emergency admission of a potential VAB. This notification shall contain a request for an authorization for admission and emergency treatment. If VA denies VAB status to such a person admitted in an emergency, the provisions of § 728.81(a) are applicable. Once admitted in an emergency situation, a VAB shall be discharged promptly upon termination of the emergency unless arrangements have been made with the VA office of jurisdiction:

(A) For transfer to a VA treatment facility if further treatment is required.

(B) To retain the patient as a VAB in the naval MTF.

(2) *Outpatient Care.* Outpatient care, including post hospitalization outpatient care, may be provided upon authorization by the VA office of jurisdiction. When outpatient followup care is requested, commanding officers are responsible for determining whether capabilities and workload permit providing such care. In an emergency, necessary care shall be provided.

(3) *Physical Examinations.* Upon a determination by a naval MTF commanding officer that space, facilities, and capabilities exist, naval MTFs may provide physical examinations when requested by the VA for the purpose of adjudicating claims for VA physical disability compensation. If authorized by the VA, patients may be admitted when the examination requires more than one day.

(4) *Dental Care.* Dental treatment shall be limited to inpatients who require services adjunctive to medical or surgical conditions for which hospitalized.

(e) *Care Outside the United States.* (1) *Eligible Beneficiaries.* Beneficiaries described in § 728.52(a) who are citizens of the United States and residing or sojourning abroad may, within the capabilities of the facility as determined by the commanding officer, be provided inpatient and outpatient care upon presentation of an authorization from the appropriate VA office of jurisdiction listed in § 728.52(e)(3).

(2) *Emergency Care.* Overseas naval MTFs furnishing emergency care to potential VABs shall promptly notify the appropriate VA office of jurisdiction and request authorization for treatment and instructions for disposition of the patient.

(3) *Offices of Jurisdiction.* The following activities are vested with the responsibility for issuing authorizations for care and furnishing disposition instructions for VABs in overseas naval MTFs:

(i) In the Trust Territory of the Pacific (Micronesia), VA Office, Honolulu, Hawaii.

(ii) In the Philippines, VA Regional Office, Manila, Philippines.

(iii) In Canada, Canadian Department of Veterans Affairs, Ottawa, Canada.

(iv) In all other foreign countries, consular offices of U.S. embassies.

(f) *Forms Required.* (1) VA Form 10-10 (Application for Medical Benefits) will be completed for those potential VABs admitted for emergency care without prior authorization.

(2) VA Form 10-10m (Medical Certificate and History) will be prepared by naval MTFs when care is rendered. All information required in the medical

certificate thereon will be furnished whether the admission is subsequently approved or disapproved by the VA office of jurisdiction.

(3) Since the completion of VA Form 10-10m requires an examination of patients, admissions which are disapproved shall be reported as medical examinations on DD Form 7A, Report of Treatment Furnished Pay Patients, Outpatient Treatment Furnished (Part B).

(4) DD Form 7, Report of Treatment Furnished Pay Patients, Hospitalization Furnished (Part A) will be prepared and submitted on all VABs and potential VABs admitted.

(5) Standard Form 502 (Narrative Summary) or Standard Form 539 (Abbreviated Clinical Record), as appropriate, will be completed when a VAB or potential VAB is discharged or otherwise released. When an interim report of hospitalization is requested by the VA office of jurisdiction, it may be prepared on Standard Form 502.

§ 728.53 Department of Labor, Office of Workers' Compensation Programs (OWCP) Beneficiaries.

(a) *Potential Beneficiaries.* The following may be beneficiaries of one of the programs sponsored by the Office of Workers' Compensation Programs (OWCP) under the conditions set forth. They are not beneficiaries of OWCP until authorized as such by the appropriate district office of OWCP. However, they may be carried as potential beneficiaries pending OWCP determination of eligibility. DOD civilian employees provided medical services under a Defense or service health program are not included under this authority (see subpart G).

(1) Members and applicants for membership in the Reserve Officers' Training Corps of the Navy, Army, and Air Force, provided the condition necessitating treatment was incurred in line of duty and the care rendered is solely after termination of duty for injury (a disease or illness which is the proximate result of performance of training is considered an injury) incurred while engaged in:

(i) Training.

(ii) Flight instructions.

(iii) Travel to or from training or flight instructions.

(2) The following employees of the Government of the United States, regardless of nationality or place of work, are entitled to receive care as outlined in § 728.53(e) for work incurred injuries, at the expense of OWCP. (In addition to injury by accident, a disease or illness which is the proximate result of performance of employment duties is

considered an injury. OWCP payment for treatment of a nontraumatic injury or a disease depends upon favorable adjudication of the case by OWCP even though the individual presents with a CA-16 signed by the individual's supervisor.) This category includes but is not limited to:

(i) Civilian student employees in training at Navy and Marine Corps facilities.

(ii) Civilian seamen in the service of vessels operated by the Department of the Army (see § 728.53(a)(7) and § 728.80(c)(2) for civilian Military Sealift Command (MSC) personnel).

(iii) All civilian employees of the Government except nonappropriated-fund-activity employees.

(3) Civilian members of the Civil Air Patrol (except Civil Air Patrol Cadets) for injury or disease which is the proximate result of active service or travel to and from such service, rendered in performance or support of operational missions of the Civil Air Patrol under the direction and written authority of the Air Force.

(4) Former Peace Corps enrollees for injury or disease which is the proximate result of their former employment with the Peace Corps or which was sustained or contracted while located with the Peace Corps outside the United States and its territories.

(5) Former Job Corps enrollees for injury or disease which is the proximate result of employment with the Jobs Corp.

(6) Former VISTA (Volunteers in Service to America) enrollees for injury or disease which is the proximate result of employment with VISTA.

(7) Military Sealift Command (MSC) civilian marine personnel (CIVMARPERs or CIVMARS) (including temporary employees, intermittent employees, and employees with less than 1 year's service) are entitled to occupationally related care at the expense of OWCP. CIVMARS are in a crew status only after reporting to their assigned ship. They are in a travel status from crewing point to ship and return. While in a travel status, they are entitled to the same health care benefits as other Federal civil service employees in a travel status (5 U.S.C. 8101). CIVMARS presenting for treatment with a properly completed CA-16, Request for Examination and/or Treatment, shall:

(i) Enter the naval MTF's system through the occupational medicine service.

(ii) Be treated for any injury or disease proximately caused by their employment. Although the actual

determination of whether an illness or injury is occupationally related is a function of OWCP, determinations are based on the injury report required in each instance along with the treatment record from the attending physician. Therefore, when doubt exists as to the relationship of the condition to the potential patient's employment, the physician should report an unbiased medical conclusion and the medical rationale therefore, indicating the conditions which are responsible for the claimant's disability. As a general rule, the following may be initially considered as occupationally related, however, it should be emphasized that OWCP is the final approval authority:

(A) Any injury or illness occurring as a direct result of employment. May occur on a ship, at a Government installation ashore, or in an aircraft while performing a requirement of employment.

(B) Any injury or illness which becomes manifest while away from work (on leave or liberty) while in a crew status or travel status as long as the condition may be directly related to job activities or to exposures incident to travel to ship assignment.

(C) Required immunizations.

(D) Required physical examinations.

(E) Periodic medical surveillance screening examinations for DOD occupational and industrial health programs, i.e., asbestos medical surveillance, hearing conservation, etc.

(iii) Be referred to a non-Federal source of care where back-to-work care may be provided at the CIVMAR's expense after, if necessary, the immediate emergency is alleviated when a reasonable determination can be made that injury or illness is not occupationally related.

(A) Pursuant to 5 U.S.C. 7901(c)(3), the health service program for Federal civilian employees is limited to referral of employees, upon their request, to private sources of care.

(B) Long term extended care of chronic illnesses such as hypertension, diabetes, etc., is not authorized in naval MTFs at the expense of OWCP nor at the CIVMAR's personal expense.

(C) Patients who cannot be referred, because of medical reasons or because non-Federal sources are not available or available but inadequate, may be retained in naval MTFs at the expense of the CIVMAR or of his or her private insurance until transfer becomes possible. Although the means of access to the naval MTF may have been through the occupational medicine service, retention in the naval MTF is on a civilian humanitarian basis. This is also applicable when OWCP disallows

a CIVMAR's claim (see § 728.53(c) below).

(b) *Authorization Required.* Personnel in § 728.53(a) (1) through (6) may be rendered inpatient and outpatient care as outlined in § 728.53(e), unless otherwise stipulated in § 728.53, upon presentation of a properly prepared and signed Authorization Form CA-16 (Request for Examination and/or Treatment). If the condition for which treatment is requested appears related to employment, treatment of beneficiaries in § 728.53(a) (1) through (7) may be initiated without said authorization. Patients provided treatment without Form CA-16 may be carried as OWCP beneficiaries from the time of initial treatment, provided the appropriate district office of OWCP is notified and requested to submit Form CA-16 within 48 hours giving authorization as of the date of actual treatment. OWCP will not be liable for the payment of bills for unauthorized treatment. Post hospitalization care following authorized inpatient care does not require an additional authorization. First aid treatment rendered civilian employees does not require an authorization form.

(c) *Disallowance by OWCP.* When OWCP determines that any claim should be disallowed, OWCP will advise the naval facility rendering care that no further treatment shall be rendered at OWCP expense. The patient ceases to be an OWCP beneficiary as of the date of receipt of the notice of disallowance by the naval MTF and the patient shall be so notified. Any treatment subsequent to the date of receipt of the notice of disallowance shall be at the personal expense of the patient (see § 728.81(a)).

(d) *Authorization for Transfer.* Prior approval of OWCP is required before a transfer can be effected, except in an emergency or when immediate treatment is deemed more appropriate in another Federal facility. When transfer is effected without approval, the transferring facility shall immediately request such authorization from the appropriate district office of OWCP. When authorized by OWCP, evacuation to the United States shall be effected in accordance with OPNAVINST 4630.25B. Medical records and Form CA-16 will accompany such patients.

(e) *Care Authorized.* (1) *Inpatient Care.* Medical and surgical care necessary for the proper treatment of the condition upon which eligibility is based. Specific OWCP authorization is required before major surgical procedures can be performed unless the urgency of the situation is such that time does not permit obtaining said

authorization. All necessary prostheses, hearing aids, spectacles, and orthopedic appliances shall be furnished when required for proper treatment of the condition upon which eligibility is based. Damaged or destroyed medical braces, artificial limbs, and other prosthetic devices shall be replaced or repaired, except that eyeglasses and hearing aids shall not be replaced or repaired unless their damage or destruction is incidental to a personal injury requiring medical services.

(2) *Outpatient Care.* Complete medical and surgical care not requiring hospitalization, and posthospitalization services following authorized inpatient care in a naval MTF for the proper treatment of the condition upon which eligibility is based.

(3) *Dental Care.* Dental treatment shall be limited to emergencies and that necessary as an adjunct to inpatient hospital care. Such care shall not include dental prostheses or orthodontic treatment.

(f) *Reports and Records.* (1) Copies of medical records will accompany OWCP patients being transferred from one medical treatment facility to another. Records accompanying OWCP patients to a debarkation hospital will be the same as for military personnel and will clearly identify the patient as an OWCP beneficiary.

(2) Form CA-20 (Attending Physician's Report) shall be forwarded to the appropriate district office of OWCP on discharge of the patient unless hospitalization exceeds 1 month. In such instances, a report shall be submitted every 30 days. When extensive hospitalization is required, use SF 502 of a narrative format in lieu of CA-20. When submitted to OWCP, the physician's report shall include:

(i) History.

(ii) Physical findings.

(iii) Laboratory findings.

(iv) Abstract of hospital records.

(v) Diagnosis for conditions due to injury and not due to injury.

(vi) Rationalized medical opinion for the physician's belief that the illness or disease treated was causally related to a specific condition or set of conditions to which the claimant was subjected.

(vii) Condition on discharge with opinion as to degree of impairment due to injury, if any.

§ 728.54 U.S. Public Health Service (USPHS), Other Than Members of the Uniformed Services.

(a) *Potential Beneficiaries.* The following may be beneficiaries of the USPHS for care in naval MTFs upon submission of the necessary form from

appropriate officials as outlined in § 728.54(b).

(1) Within and Outside the United States. Any individuals the USPHS may determine to be eligible for care on an interagency reimbursable basis.

(2) Within the 48 Contiguous United States and the District of Columbia. American Indians, Alaskan Natives, Eskimos, and Aleuts.

(3) In Alaska. American Indians, Eskimos, and Aleuts.

(b) *Authorization Required.* (1) *Normal Circumstances.* An American Indian or Alaskan Native may be rendered inpatient care upon presentation of HRSA Form 43 (Contract Health Service Purchase Order for Hospital Services Rendered) or HRSA Form 64 (Purchase/Delivery Order for Contract Health Services Other Than Hospital Inpatient or Dental). Either form must be signed by an appropriate Indian Health Service or Alaska Native Health Service area official.

(2) *Emergencies.* In an emergency, care may be rendered upon written request of patient's commanding officer or superior officer, or the patient if neither of the above is available. When emergency care is rendered without prior authorization, the facility rendering care must notify the service unit director of the patient's home reservation within 72 hours from the time such care is rendered unless extenuating circumstances preclude prompt notification.

(c) *Care Authorized.* Unless limited by the provisions stipulated in § 728.54(a) and subject to the provisions of § 728.3, the following care may be rendered, when requested, to all beneficiaries enumerated in § 728.54(a).

(1) *Inpatient Care.* Necessary medical and surgical care.

(2) *Outpatient Care.* Necessary medical and surgical care.

(3) *Dental Care.*

(i) Dental care in the United States, its territories, possessions, and the Commonwealth of Puerto Rico is limited to emergencies for the relief of pain or acute conditions and that necessary as an adjunct to inpatient hospital care. Prosthetic dental appliances and permanent restorations are not authorized.

(ii) In overseas areas, dental care is authorized to the extent necessary pending the patient's return to the United States, its territories, possessions, or the Commonwealth of Puerto Rico.

§ 728.55 Department of Justice Beneficiaries.

Upon presentation of a letter of authorization that includes disposition

of SF 88 (Report of Medical Examination), SF 93 (Report of Medical History), and address for submission of claim, the following personnel may be furnished requested care as beneficiaries of the Department of Justice.

(a) *Federal Bureau of Investigation.* Investigative employees of the Federal Bureau of Investigation (FBI) and applicants for employment as special agents with the FBI may be provided:

(1) Immunizations.

(2) Physical examinations and hospitalization when required to determine physical fitness. This period of hospitalization shall be used for diagnostic purposes only, and not to correct disqualifying defects.

(b) *U.S. Marshals.* U.S. Marshals may receive physical examinations and hospitalization when required to determine physical fitness. This period of hospitalization shall be used for diagnostic purposes only, and not to correct disqualifying defects.

(c) *Claimants Against the United States.* Claimants whose suits or claims against the United States are being defended by the Department of Justice may be furnished physical examinations to determine the extent and nature of the injuries or disabilities being claimed. Hospitalization is authorized for proper conduct of the examination. Upon completion, the report of the examination shall be furnished promptly to the U.S. Attorney involved.

§ 728.56 Treasury Department Beneficiaries.

(a) *Potential Beneficiaries.* The following may be beneficiaries of the Treasury Department and may be rendered care as set forth below.

(1) Secret Service Special Agents.

(2) Secret Service Agents providing protection to certain individuals.

(3) Persons being provided protection by the Secret Service.

(4) Agents of the U.S. Customs Service.

(5) Prisoners (detainees) of the U.S. Customs Service.

(b) *Care Authorized.* (1) Secret Service Special Agents may be provided routine annual physical examinations upon request and presentation of a letter of authorization. Such examinations shall be conducted and recorded in the same manner as routine examinations rendered naval officers except that they shall be conducted on an outpatient basis only. If hospitalization is considered desirable in connection with the examination, a statement to that effect will be entered in item 73 or 75 of the SF 88, as appropriate, before

forwarding to the Director, United States Secret Service.

(2) Secret Service Agents providing protection to certain individuals and those persons being provided such protection shall be rendered all required medical services including hospitalization subject to the provisions of § 728.3.

(3) Agents of the U.S. Customs Service and their prisoners (detainees) may be provided emergency medical treatment and evacuation services to the nearest medical facility (military or civilian) in those remote areas of the United States where no other such services are available. Evacuation will be limited to the continental United States and borders will not be crossed. The Navy's responsibility for medical care of such prisoners terminates once the medical emergency has been resolved. The guarding of prisoners, while they or their captors are receiving treatment at naval MTFs, remains the responsibility of the U.S. Customs Service or other appropriate Federal (nonmilitary) law enforcement agencies.

(c) *Reports and Records.* When examinations are rendered to Secret Service Special Agents, one copy of the SF 88 and one copy of the SF 93 shall be forwarded to the Director, United States Secret Service, Personnel Division, Employee Relations Branch, 1800 G Street, NW., Room 941, Washington, DC 20223 or as otherwise directed by the letter of authorization. An information copy shall be provided to the Deputy Comptroller of the Navy.

§ 728.57 Department of State and Associated Agencies.

Eligibility for care under the provisions of § 728.58 shall be determined by the Department of State, Office of Medical Services.

(a) *Beneficiaries.* Officers and employees of the following agencies, their dependents, and applicants for appointment to such agencies are authorized inpatient and outpatient medical care as set forth below in addition to that care that may be authorized elsewhere within this instruction (i.e., § 728.53, 728.55, 728.56, and 728.58). Dental care shall be limited to that delineated in § 728.57(b)(6).

(1) Department of State—U.S. Arms Control and Disarmament Agency and the Office of International Conferences.

(2) U.S. Agency for International Development.

(3) International Communications Agency.

(4) ACTION—Peace Corps Staff.

(5) Department of Agriculture—Foreign Agriculture Service.

(6) Department of Commerce—Bureau of Public Roads.

(7) Department of Interior—Bureau of Reclamation and the U.S. Geological Survey.

(8) Department of Transportation—Federal Aviation Administration and the Federal Highway Administration.

(9) Department of Justice—Drug Enforcement Agency.

(10) Department of Treasury—U.S. Customs, U.S. Secret Service, Office of International Affairs (OIA), U.S.-Saudi Arabian Joint Commission for Economic Cooperation (JECOR), and the Internal Revenue Service.

(11) National Aeronautics and Space Administration.

(12) Library of Congress.

(13) Beneficiaries of such other agencies as may be included in the Department of State Medical Program.

(b) *Care Authorized.* (1) *General.* Care delineated below is authorized by the Foreign Service Act of 1946, as amended. Subject to the restrictions and priorities of § 728.3 and the restrictions of § 728.57, care may be rendered at naval MTFs at the expense of the Department of State or one of the agencies listed in § 728.57(a). The law allows for payment when care is furnished for an illness or injury which results in hospitalization or equal treatment. Out-patient care is only authorized as an adjunct to hospitalization.

(2) *Overseas.*

(i) When, in the opinion of the principal or administrative officer of an overseas post of the Department of State, an individual meets the conditions of eligibility, the post will furnish authorization to the naval MTF for care at the expense of the Department of State or one of the agencies listed above.

(ii) Should the Department of State official determine that the illness or injury does not meet the conditions of eligibility for care at the expense of one of the agencies, all care provided shall be at the expense of the patient or patient's sponsor and charged at the full reimbursement rate.

(3) *In the United States.*

(i) Care is not authorized for an injury or illness incurred in the United States. Authorizations and other arrangements for care in the United States for individuals incurring injury or illness outside the United States will be provided by the Deputy Assistant Secretary for Medical Services, Department of State, using appropriate authorization form(s). When personnel are admitted in an emergency without prior authorization, the commanding officer of the admitting naval MTF shall

immediately request authorization from the Deputy Assistant Secretary for Medical Services.

(ii) The extent of care furnished in the United States, to individuals above who are evacuated to the United States for medical reasons, will be comparable in all respects to that which is authorized or prescribed for these individuals outside the United States. When determined appropriate by the Deputy Assistant Secretary for Medical Services, officers and employees and their accompanying dependents who have returned to the United States for nonmedical reasons may be furnished medical care at the expense of one of the above agencies for treatment of an illness or injury incurred while outside the United States.

(4) *Physical Examinations.* The Secretary of State is authorized to provide for comprehensive physical examinations, including dental examinations and other specific testing, of applicants for employment and for officers and employees of the Foreign Service who are U.S. citizens and for their dependents, including examinations necessary to establish disability or incapacity for retirement purposes. An authorization will be executed by an appropriate Department of State official and furnished in duplicate to the naval MTF, listing the type of examination required and stating that the individual is entitled to services at the expense of the Department of State. Reports shall be furnished in accordance with the letter of authorization.

(5) *Immunizations.* Inoculations and vaccinations are authorized for officers, employees, and their dependents upon written authorization from an appropriate Department of State official. This authorization, in duplicate, will include the type of inoculation or vaccination required and shall state that the individual is entitled to services at the expense of the Department of State. Reports shall be furnished in accordance with the letter of authorization.

(6) *Dental Care.* Dental care at the expense of the Department of State is limited to emergency care for the relief of pain or acute conditions, or for dental conditions as an adjunct to inpatient care. Such care will not include the provision of prosthetic dental appliances.

(c) *Evacuation to the United States.* Should a beneficiary in an overseas naval MTF require prolonged hospitalization, the commanding officer of the overseas facility shall report the requirement to the nearest Department of State principal or administrative officer and request authority to return

the patient to the United States. Dependents in such instances who decline evacuation shall be released to the custody of their sponsor. Aeromedical evacuation may be used in accordance with OPNAVINST 4630.25B. Travel of an attendant or attendants is authorized at Department of State expense when the patient is too ill or too young to travel unattended.

§ 728.58 Federal Aviation Administration (FAA) Beneficiaries.

(a) *Beneficiaries.* Air Traffic Control Specialists (ATCS) of the FAA when appropriate authorization has been furnished by the FAA regional representative.

(b) *Authorization.* Written authorization from an FAA Regional Flight Surgeon is required and it shall include instructions for forwarding the results of services rendered.

(c) *Care Authorized.* Subject to the provisions of § 728.3, authorized personnel shall be rendered chest x-rays, electrocardiograms, basic blood chemistries, and audiograms, without interpretation in support of the medical surveillance program for ATCS personnel established by the FAA.

§ 728.59 Peace Corps Beneficiaries.

(a) *Potential Beneficiaries.*

- (1) Applicants for the Peace Corps.
- (2) Peace Corps Volunteers.
- (3) Applicants for the Peace Corps.
- (2) Minor children of a Peace Corps volunteer living with the volunteer.

(b) *Care Authorized in the United States.* Upon written request of a Peace Corps official, stating care to be provided and disposition of reports, the following may be provided subject to the provisions of § 728.3.

(1) *Physical Examinations.* Pursuant to BUMEDINST 6120.17B, physical examinations are authorized on an outpatient basis only. Except as outlined in BUMEDINST 6120.17B, no assessment will be made of the physical qualifications of examinees.

(i) Preselection physical examinations may be provided applicants (volunteers) for the Peace Corps.

(ii) Separation or other special physical examinations may be provided volunteers and their dependents as listed in § 728.59(a)(3).

(2) *Immunizations.* Immunizations, as requested, may be provided all beneficiaries listed in § 728.59(a).

(3) *Medical Care.* Both inpatient and outpatient care may be provided volunteers for illnesses or injuries occurring during their period of service which includes all periods of training. Dependents of volunteers specified in

§ 728.59(a)(3) are authorized care to the same extent as their sponsor.

(4) *Dental Care.* Dental care is limited to emergencies. Only that care essential to relieve pain or prevent imminent loss of teeth shall be rendered. All beneficiaries seeking dental care shall be requested, whenever possible, to furnish advanced authorization for such care.

(c) *Care Authorized Outside the United States.* (1) *Physical Examinations.* Termination physical examinations may be provided volunteers and eligible dependents of volunteers. In most instances, these examinations will be provided by Peace Corps staff physicians; however, assistance may be required of naval MTFs for ancillary services (see BUMEDINST 6120.17B).

(2) *Immunizations.* When requested, immunizations may be provided all beneficiaries listed in § 728.59(a).

(3) *Medical Care.* When requested in writing by a representative or physician of a Peace Corps foreign service post, volunteers, eligible dependents of volunteers, and trainees of the Peace Corps may be provided necessary medical care at Peace Corps expense. When emergency treatment is rendered without prior approval, a request shall be forwarded to the Peace Corps foreign service post as soon as possible.

(4) *Dental Care.* Dental care is limited to emergencies. Only that care essential to relieve pain or prevent imminent loss of teeth shall be rendered. Beneficiaries seeking dental care shall be requested, whenever possible, to furnish advanced authorization for such care.

(5) *Evacuation to the United States.* When a beneficiary in an overseas naval MTF requires prolonged hospitalization, the commanding officer of the overseas facility shall report the requirement to the nearest Peace Corps foreign service post and request authorization to return the patient to the United States. Dependents in such instances who decline evacuation shall be released to the custody of their sponsor. Aeromedical evacuation may be utilized in accordance with OPNAVINST 4630.25B. Travel of attendant(s) is authorized when the patient is too ill or too young to travel unattended. (Symbol OPNAV 4630-1 applies.)

§ 728.60 Job Corps and Volunteers in Service to America (VISTA) Beneficiaries.

(a) *Beneficiaries.* Job Corps and VISTA enrollees and applicants may be provided services as set forth. For former members, see § 728.53.

(b) *Authorization Required.* (1) Job Corps Enrollees. Presentation of a Job

Corps Identification Card after appointment has been made by the corpsmember's Job Corps center.

(2) *Job Corps Applicants.* Presentation of a letter from a screening agency (e.g., State Employment Service) after an appointment has been made by that agency.

(3) *VISTA Volunteers and VISTA Trainees.* A valid "Blue-Cross and Blue Shield Identification Card" is issued to such personnel as identification. Each card has a VISTA identification number which shall be used on all records and correspondence.

(c) *Care Authorized.* Normally, medical services are provided only when civilian or VA facilities are not available, or if available, are incapable of providing needed services. However, upon presentation of appropriate authorization, the following services may be rendered subject to the provisions of § 728.3.

(1) Job Corps enrollees are authorized emergency medical care upon presentation of their Job Corps Identification Card, however, the corpsmember's Job Corps center should be notified immediately.

(2) Job Corps application may be provided pre-enrollment physical examinations and immunizations on an outpatient basis only.

(3) Job Corps enrollees, VISTA trainees, and VISTA volunteers are authorized:

(i) Outpatient medical examinations, outpatient treatment, and immunizations.

(ii) Inpatient care for medical and surgical conditions which, in the opinion of the attending physician, will benefit from definitive care within a reasonable period of time. When it is found probable that a patient will require hospitalization in excess of 45 days, the Commander, Naval Medical Command (MEDCOM-33) shall be notified by the most expeditious means.

(iii) Dental care is limited to emergencies. Only that care essential to relieve pain or prevent imminent loss of teeth shall be rendered. Beneficiaries seeking dental care shall be requested to furnish, whenever possible, advanced authorization for such care.

§ 728.61 Medicare beneficiaries.

(a) *Care Authorized.* Hospitalization is authorized for beneficiaries who reside in the 50 United States and the District of Columbia, Guam, Puerto Rico, the Virgin Islands, American Samoa, and the Northern Mariana Islands. Such hospitalization shall be rendered when emergency services are necessary to prevent death or serious impairment to the health of the individual and which,

because of the threat to life or health, necessitates the use of the most accessible hospital that is equipped to furnish such services. Such care is authorized beneficiaries of the Social Security Health Insurance Program for the Aged and Disabled (Medicare).

(b) *General Provisions.* (1) *Limitations.* Benefit payments for emergency services under Medicare can be made for only that period of time during which the emergency exists. Therefore, when the emergency is terminated and it is permissible from a medical standpoint, the patient should be discharged or transferred to a facility that participates in Medicare.

(2) *Notification.* The nearest office of the Social Security Administration shall be notified as soon as possible when a Medicare beneficiary is rendered treatment.

Subpart G—Other Persons

§ 728.71 Ex-service maternity care.

(a) *Eligible Beneficiaries.* Former women members of the Armed Forces who have been separated from active duty under honorable conditions because of pregnancy, or separated from the service under honorable conditions for reasons other than pregnancy and found to have been pregnant at the time of separation, and their newborn infant(s) may be provided care as set forth in § 728.71, subject to the provisions of § 728.3. When certified by medical authorities that the pregnancy existed prior to entry into service (EPTE), maternity benefits are not authorized.

(b) *Care Authorized.* (1) Former women members shall be rendered medical and surgical care in naval MTFs incident to that pregnancy, prenatal care, hospitalization, postnatal care, and, when requirements of SECNAVINST 6300.2A are met, abortions. Postnatal care is limited to 6 weeks following delivery. Under no circumstances will care from civilian sources be promised for either the mother or the infant as it is not authorized.

(2) Treatment of the newborn infant in USMTFs includes care, both inpatient and outpatient, only during the first 6 weeks (42 days) following delivery. If the newborn infant requires care beyond the 6-week postnatal period, arrangement shall be made by the mother, or other responsible family member, for disposition to private, State, welfare, or other Federal facility.

(c) *Application for Care.* In making application for care authorized by § 728.71, former women members should

apply either in person or in writing to the Armed Forces inpatient MTF nearest their home and present either their DD Form 214 (Armed Forces of the United States Report of Transfer or Discharge) or DD Form 256A (Honorable Discharge Certificate) as proof of eligibility for requested care. In areas with more than one Armed Forces MTF available and capable of providing required care, application should be made to the MTF of the service from which separated. Referral to other services MTFs may be made only when space is not available or capability does not exist in the MTF of the service from which the individual was separated.

§ 728.72 Applicants for Enrollment in the Senior Reserve Officers' Training Program.

When properly authorized, designated applicants (including applicants for enrollment in the 2-year program and Military Science II enrollees applying for Military Science III) may be furnished medical examinations at naval MTFs including hospitalization necessary for the proper conduct thereof. Medical care, including hospitalization, is authorized for diseases contracted or injuries incurred in line of duty while at or traveling to or from a military installation for the purpose of undergoing medical or other examinations or for visits of observation.

§ 728.73 Applicants for Enlistment or Reenlistment in the Armed Forces, and Applicants for Enlistment in the Reserve Components.

(a) Upon referral by a commander of a Military Enlistment Processing Station (MEPS), formerly Armed Forces Examining and Entrance Station (AFES), applicants shall be furnished necessary medical examinations, including hospitalization when qualifications for service cannot otherwise be determined. Such a period of hospitalization shall be used only for diagnostic purposes, and not to correct disqualifying defects.

(b) Applicants who suffer injury or acute illness while awaiting or undergoing processing at Navy and Marine Corps facilities or MEPS may be furnished emergency medical and dental care, including emergency hospitalization, for that injury or illness.

§ 728.74 Applicants for Appointment in the Regular Navy or Marine Corps and Reserve Components, Including Members of the Reserve Components Who Apply for Active Duty.

(a) Necessary medical examinations shall be furnished, including hospitalization when qualifications for service cannot otherwise be determined.

Such a period of hospitalization shall be used only for diagnostic purposes, and not to correct disqualifying defects.

(b) Applicants who suffer injury or acute illness while awaiting or undergoing processing at Navy and Marine Corps facilities or MEPS may be furnished emergency medical and dental care, including emergency hospitalization, for that injury or illness.

§ 728.75 Applicants for Cadetship at Service Academies and Applicants for the Uniformed Services University of Health Sciences (USUHS).

(a) Upon presentation of a letter of authorization from the Department of Defense Medical Examination Review Board (DODMERB), applicants for cadetship at Service Academies (Navy, Army, Air Force, Coast Guard, and Merchant Marine) and applicants for the Uniformed Services University of Health Sciences (USUHS) shall be furnished medical examinations at facilities designated by the DODMERB. Hospitalization is authorized when qualifications for service cannot otherwise be determined. Such a period of hospitalization shall be used for diagnostic purposes only, and not to correct disqualifying or other defects. Examinations shall be performed and disposition of completed forms made in accordance with BUMEDINST 6120.3M.

(b) Applicants who suffer injury or acute illness while awaiting or undergoing processing at Navy and Marine Corps facilities or at MEPS may be furnished emergency medical and dental care, including emergency hospitalization, for that injury or illness.

§ 728.76 Naval Home Residents.

Necessary medical and dental care, both inpatient and outpatient, shall be furnished residents of the Naval Home when requested by the Governor of the Home. In an emergency, care may be rendered without prior approval of the Governor; however, the Governor of the Home should be contacted immediately and requested to furnish authorization.

§ 728.77 Secretarial Designees.

(a) Upon a showing of sufficient cause, the Secretary of the Navy may authorize individuals, not otherwise authorized by law, to receive such care as is available in naval MTFs in the United States. This discretionary authority is exercised most conservatively, on an individual basis. Civilian health care however cannot be authorized. Favorable action is usually taken on requests involving the following situations:

(1) Preadoption proceedings wherein an active duty member or a retired

member has taken affirmative action to adopt a child.

(2) Custodianships and guardianships authorized by a court order wherein the member is designated by the court as the custodian or guardian and the child is fully dependent upon the active duty or retired member sponsor.

(3) Evaluation and selection of nonbeneficiaries who are donor candidates for an organ or tissue transplant procedure in behalf of a military service beneficiary.

(4) Nonbeneficiary participants in officially approved clinical research studies.

(5) Designation of designees of other military departments.

(6) Unmarried former spouses:

(i) Divorced before 1 February 1983, and

(ii) On the date of the final decree of divorce, dissolution, or annulment, has been married to the active duty or retired member for 20 or more years during which time the member or former member performed at least 20 years of service creditable in determining that member's or former member's eligibility for retired or retainer pay, or equivalent pay, and

(iii) Requires care for a condition incurred during or caused/aggravated by conditions associated with the member's or former member's creditable service, and

(iv) Does not have medical coverage under an employer-sponsored health plan which will provide for the care required.

(7) In other instances wherein the circumstances clearly merit the providing of treatment in naval MTFs, and in which the best interest of the patient, the Navy, and the Government will be served, favorable Secretarial action may result. The mere need of medical care by a former beneficiary or other person, alone, will not support approval of such a request.

(b) Requests for consideration shall be submitted to the Commander, Naval Medical Command (MEDCOM-33) by applicants via their command, when applicable, or by the Medical Department command concerned. Requests should include any pertinent information which will support resolution requests:

(1) Involving preadoption must include a legible reproducible copy of the court order which names the sponsor and identifies the other participating parties.

(2) Involving custodianships and guardianships must include a legible reproducible copy of the court order, identification of the parties, and also

identify any amounts of income to which the ward is entitled.

(3) In behalf of participants in clinical research studies must include:

(i) Sufficient clinical information concerning the nature of the study.

(ii) Benefits which may accrue to the individual.

(iii) The extent, if any, to which access by other authorized beneficiaries will be impaired.

(iv) Benefits which will accrue to the command, e.g., enhancement of training, maximum utilization of specialized facilities, etc.

(v) Recommended duration of designation.

(vi) Whether the consenting individual has been informed concerning the nature of the study, its personal implications, and freely consents.

(4) In behalf of unremarried former spouses must include:

(i) A notarized copy of the marriage license.

(ii) A statement attesting to the fact that the former husband achieved 20 or more years of creditable military service during the time of the marriage.

(iii) Copy of divorce decree with official date.

(c) Secretarial designee status has been granted by the Secretary of Defense for full-time Schedule "A" faculty members of the Uniformed Services University of Health Sciences (USUHS) who have been provided documentation substantiating their eligibility and, where necessary, an eligibility termination date. These personnel are authorized routine care at the Naval Hospital, Bethesda, MD. Only emergency treatment is authorized these personnel at other naval MTFs while they are traveling on official university business. The letter of authorization excludes routine dental care, prosthetic appliances, and spectacles.

(d) The following civilian officials within the Government, the Department of Defense, and military departments have been granted blanket Secretarial designation for medical and emergency dental care in naval MTFs in the United States at interagency inpatient and outpatient rates. EXCEPTION: Charges for outpatient care provided in the National Capital Region shall be waived:

- (1) The President.
- (2) The Vice President.
- (3) Members of the Cabinet.
- (4) Article III Federal Judges.
- (5) U.S. Court of Military Appeals Judges.
- (6) Members of Congress.
- (7) The Secretary, Deputy Secretary, and the Assistant Secretaries of Defense.

(8) The Under Secretary of Defense for Policy.

(9) The Under Secretary of Defense for Research and Engineering.

(10) The Secretaries, Under Secretaries, and the Assistant Secretaries of the Military Departments.

§ 728.78 American Red Cross Representatives and Their Dependents.

(a) *Potential Beneficiaries.*

(1) Volunteer workers.

(2) Full-time, paid employees.

(3) Dependents of personnel enumerated in § 728.78(a) (1) and (2) when accompanying their sponsor outside the continental United States or in Alaska.

(b) *Care Authorized.* (1) When services of the American Red Cross (ARC) have been accepted in behalf of the Federal Government under applicable DOD regulations, beneficiaries in § 728.78(a)(1) are considered "employees" of the Government for the purpose of this part and are authorized health care in USMTFs, both in and outside the United States for work-related conditions. See § 728.53(a)(2) regarding the specific application of this authorization.

(2) Beneficiaries enumerated in § 728.78(a) (1) and (2) are authorized health care in USMTFs located outside the United States on a reimbursable basis for both work and nonwork-related conditions. Those enumerated in § 728.78(a)(1), however, are not required to reimburse the Government for treatment of work-related conditions under the OWCP (see § 728.53(a)(2)).

(3) Beneficiaries identified in § 728.78(a) (1), (2), and (3) are authorized emergency care on a reimbursable basis in USMTFs outside the continental United States and in Alaska where facilities are not otherwise available in reasonably accessible and appropriate non-Federal hospitals. Hospitalization shall be furnished only for acute medical and surgical conditions, exclusive of nervous, mental, or contagious diseases or those requiring domiciliary care. Dental treatment shall be administered only as an adjunct to inpatient hospital care and shall not include dental prosthesis or orthodontia.

(c) *Records Disposal.* Upon completion of treatment of accredited representatives of the American Red Cross or their dependents, medical records, including all clinical records and x-ray films, shall be forwarded to the Medical Director, National Headquarters, American Red Cross, 20th and D Streets, N.W., Washington, DC 20006.

§ 728.79 Employees of Federal Contractors and Subcontractors.

(a) *Beneficiaries.* (1) U.S. citizen contractor, engineering, and technical service personnel designated as U.S. Navy Technicians.

(2) Civilian employees of contractors and subcontractors operating under U.S. Government contracts.

(3) Dependents of personnel enumerated in § 728.79(a) (1) and (2) when accompanying their sponsor outside the continental United States or in Alaska.

(b) *Care Authorized.* (1) Beneficiaries identified in § 728.79(a) (1) and (2) may be provided emergency care in naval MTFs, on a reimbursable basis, for illnesses and injuries occurring at work in or outside the United States.

(2) While serving outside the continental United States or in Alaska, where facilities are not otherwise available in reasonably accessible and appropriate non-Federal hospitals, beneficiaries identified in § 728.79(a) (1), (2), and (3) may receive hospitalization and necessary outpatient services in naval MTFs on a reimbursable basis. Except for beneficiaries in § 728.79(a)(1) who are serving aboard naval vessels, all other enumerated beneficiaries may only be hospitalized for acute medical and surgical conditions, exclusive of nervous, mental, or contagious diseases or those requiring domiciliary care. Dental treatment shall be administered only as an adjunct to inpatient hospital care and shall not include dental prosthesis or orthodontia.

§ 728.80 U.S. Government Employees.

(a) Civil service employees of all Federal agencies, including teachers employed by the Department of Defense Dependents' Schools (DODDS), and their dependents may be provided hospitalization and necessary outpatient services, on a reimbursable basis, outside the continental limits of the United States and in Alaska, where facilities are not otherwise available in reasonably accessible and appropriate non-Federal hospitals. Except for employees who are serving aboard naval vessels, hospitalization shall be furnished only for acute medical and surgical conditions, exclusive of nervous, mental, or contagious diseases or those requiring domiciliary care. Dental treatment shall be administered only as an adjunct to inpatient hospital care and shall not include dental prosthesis or orthodontia.

(b) Such civilian employees and their dependents may be provided medical, surgical, dental treatment, hospitalization, and optometric care on

a reimbursable basis at installations in the United States which have been designated remote by the Secretary of the Navy for the purpose of providing medical care.

(c) The major objective of the following programs for civil service employees, regardless of location, is emergency treatment to relieve minor ailments or injuries with the idea of keeping the employee on the job:

(1) The Department of Labor, Office of Workers' Compensation Programs (OWCP) governs the overall medical care program for employees of the Government who sustain injuries while in the performance of duty, including diseases proximately caused by conditions of employment (see § 728.53).

(2) Federal civil service employees and applicants for such employment are authorized services as outlined in chapter 22, section XIII, of the Manual of the Medical Department. Military Sealift Command (MSC) civilian marine personnel (authorized additional care and services as outlined in BUMEDINST 6320.52 and that care in § 728.53(a)(7)) and members of the National Oceanic and Atmospheric Administration (NOAA) serving with the Navy are also included.

(3) Under the technical control of the Surgeon General of the Army, the DOD Civilian Employees' Health Service is responsible for administering the health program for all Federal civil service employees in the District of Columbia area.

§ 728.81 Other Civilians.

(a) *General.* In an emergency, any person may be rendered care in naval MTFs to prevent undue suffering or loss of life or limb. Care shall be limited to that necessary only during the period of the emergency, and if further treatment is indicated, action shall be initiated to transfer the patient to a private physician or civilian facility as soon as possible. Further, subject to the provisions of § 728.3, the following personnel are authorized care as set forth.

(b) *Beneficiaries and Extent of Care.*

(1) Civilian employees paid for nonappropriated funds, including Navy exchange employees and service club employees, shall be provided all occupational health services. Treatment of occupational illnesses and injuries other than emergency care shall be in accordance with rules and regulations of the Office of Workers' Compensation Programs (see § 728.53).

(2) Civilians attending the Federal Bureau of Investigation (FBI) Academy, Marine Corps Development and Education Command, Quantico, VA may

be rendered care at the Naval Medical Clinic, Quantico, VA for emergencies. Such persons who are in need of hospitalization for injuries or disease may be hospitalized and classed as civilian humanitarian nonindigents with the approval of the cognizant hospital's commanding officer. EXCEPTION:

Certain individuals, such as employees of the Federal Bureau of Investigation who are injured in the line of duty, may be entitled to care at the expense of the Office of Workers' Compensation Programs (OWCP) (see § 728.53).

(3) The following civilians who are injured or become ill while participating in Navy or Marine Corps sponsored sports, recreational or training activities may be rendered care on a temporary (emergency) basis until such time as disposition can be effected to an appropriate source.

(i) Members of the Naval Sea Cadet Corps.

(ii) Junior ROTC/NDCC (National Defense Cadet Corps) cadets.

(iii) Civilian athletes training or competing as part of the U.S. Olympic effort.

(iv) Civilians competing in Navy or Marine Corps sponsored competitive meets.

(v) Members of Little League teams and Youth Conservation groups.

(vi) Boy Scouts and Girl Scouts of America.

(4) Other civilian personnel included below are not normally eligible for care in naval MTFs; however, under the conditions set forth, care may be rendered.

(i) Potential Beneficiaries.

(A) Civilian representatives of religious groups.

(B) Educational institutions representatives.

(C) Athletic clinic instructors.

(D) USO representatives.

(E) Celebrities and entertainers.

(F) Social agencies representatives.

(G) Others in a similar status to those in § 728.81(b)(4)(i) (A) through (F).

(H) News correspondents.

(I) Commercial airline pilots and employees.

(J) Volunteer workers. This category includes officially recognized welfare workers, other than Red Cross.

(ii) Care Authorized.

(A) Persons enumerated in § 728.81(b)(4)(i) (A) through (G), who are contracted to provide direct services to the Armed Forces and who are acting under orders issued by the Department of Defense or one of the military departments to visit military commands overseas, and their accompanying dependents, may be provided medical care in naval MTFs outside the 48

contiguous United States and the District of Columbia provided local civilian facilities are not reasonably available or are inadequate. Inpatient care shall be limited to acute medical and surgical conditions exclusive of nervous, mental, or contagious diseases, or those requiring domiciliary care. Dental treatment shall be administered only as an adjunct to inpatient hospital care and shall not include dental prostheses or orthodontia.

(B) Persons enumerated in § 728.81(b)(4)(i) (H) and (I) are authorized emergency medical and dental care in naval MTFs outside the 48 contiguous United States and the District of Columbia provided local civilian facilities are not reasonably available or are inadequate.

(C) Persons enumerated in § 728.81(b)(4)(i) (J), both within and outside the 48 contiguous United States and the District of Columbia, may receive care in naval MTFs for injuries or diseases incurred in the performance of duty as beneficiaries of OWCP (see § 728.53). Additionally, if such volunteers are sponsored by an international organization (e.g., the United Nations) or a voluntary nonprofit-relief agency registered with and approved by the Advisory Committee on Voluntary Aid (e.g., CARE), they may receive other necessary nonemergency medical care and occupational health services on a reimbursable basis while serving outside the 48 contiguous United States and the District of Columbia.

§ 728.82 Individuals Whose Military Records are Being Considered for Correction.

Individuals who require medical evaluation in connection with consideration of their individual circumstances by the Navy, Army, and Air Force board or Correction of Military Records are authorized evaluation, including hospitalization when necessary for the proper conduct thereof.

728.83 Persons in Military Custody and Nonmilitary Federal Prisoners.

(a) Potential Beneficiaries.

(1) Military prisoners.

(2) Nonmilitary Federal prisoners.

(3) Enemy prisoners of war and other detained personnel.

(b) Care Authorized.

(1) Military Prisoners:

(i) Whose punitive discharges have been executed but whose sentences have not expired are authorized all necessary medical and dental care.

(ii) Whose punitive discharges have been executed and who require hospitalization beyond expiration of sentences are not eligible for care but may be hospitalized as civilian humanitarian nonindigents until final disposition can be made to some other appropriate facility.

(iii) On parole pending completion of appellate review or whose parole changes to an excess leave status following completion of sentence to confinement while on parole are members of the military service and as such are authorized care as outlined in subpart B. An individual on parole whose punitive discharge has been executed is not a member of the military service and is therefore not entitled to care authorized by § 728.82. If the circumstances are exceptional, individuals herein who are not authorized care may request Secretarial designee status under the provisions of § 728.77.

(2) Nonmilitary Federal Prisoners. Under the provisions of § 728.62, nonmilitary Federal prisoners are authorized only emergency medical care. When such care is being rendered, the institution to which prisoners are sentenced must furnish necessary guards to effectively maintain custody of prisoners and assure the safety of other patients, staff members, and residents of the local area. Under no circumstances will military personnel be voluntarily utilized to guard or control such prisoners. Upon completion of emergency care, arrangements will be made immediately to transfer the prisoners to a nonmilitary MTF or to return the prisoners to the facility to which sentenced.

(3) Enemy Prisoners of War and Other Detained Personnel. Subject to the provisions of § 728.3, enemy prisoners of war and other detained personnel are entitled to and may be rendered all necessary medical and dental care.

Subpart H—Adjuncts to Medical Care

§ 728.91 General.

Adjuncts to medical care include but are not limited to prosthetic devices such as artificial limbs, artificial eyes, hearing aids, orthopedic footwear, spectacles, wheel chairs, hospital beds, and similar medical support items or aids which are required for the proper care and management of the condition being treated. Generally, the expenses incurred for procurement of such items, either from civilian sources as supplemental care or from stocks

maintained by the facility, are payable from operation and maintenance funds available for the support of naval MTFs. However, certain adjuncts may be cost-shared under CHAMPUS for CHAMPUS-eligible individuals under the circumstances enumerated in the cooperative care or service criteria of § 728.4(aa).

§ 728.92 Policy.

(a) Adjuncts to medical care shall be provided at naval MTFs to eligible beneficiaries receiving inpatient or outpatient care when, in the opinion of the attending physician, such adjuncts will offer substantial assistance in overcoming the handicap or condition and thereby contribute to the well-being of the beneficiary.

(b) Unless necessary for humanitarian reasons, orthopedic and prosthetic appliances are not to be furnished on an elective basis to members of the naval service with short periods of service remaining when the defect requiring the appliance existed prior to entry into service and when such members are to be separated from the service because of these defects.

(c) For active duty members, the initial allowance of orthopedic footwear and orthopedic alterations to standard footwear shall be in the same quantity

as provided in the initial clothing allowance.

(d) The number of orthopedic and prosthetic appliances issued or replaced for other authorized recipients shall be based upon the individual's requirements as determined by the attending physician and shall be consistent with the highest standards of modern medicine.

(e) Former members of the uniformed service should be advised that they may obtain durable medical equipment, medical care, and adjuncts from Veterans Administration facilities.

(f) Dependents are authorized certain adjuncts in accordance with the provisions of § 728.32 and in instances where items are not normally authorized at the expense of the Government, they may be provided at cost to the United States if available from Government stocks under the following conditions:

- (1) Outside the United States.
- (2) At specific stations within the United States which have been authorized by the Secretary of the Navy to sell these items.

§ 728.93 Chart of Adjuncts.

The following chart and footnotes provide information relative to adjuncts which may be furnished the several categories of beneficiaries eligible for medical care at naval MTFs.

Adjuncts	Active duty and retired members	Others authorized the same benefits as active duty or retired members ¹	Dependents authorized the same benefits	Other beneficiaries ²
Ambulance Service	Yes	Yes	Yes ³	No
Artificial Eyes	Yes	Yes	Yes	Maybe ⁴
Artificial Limbs	Yes	Yes	Yes	Maybe ⁴
Contact or Special Lenses ⁵	Yes ⁶	Yes ⁶	Maybe ^{7,8,9}	No
Crutches ¹⁰	Yes	Yes	Yes	Yes
Dental Prostheses	Yes	Yes	Maybe ⁹	Maybe ⁹
Elastic Stockings	Yes	Yes	Yes	Yes
Hearing Aids ¹¹	Yes ⁶	Yes ⁶	Maybe ⁹	Maybe ⁹
Hearing Aid Parts and Batteries	Yes ¹²	Yes ¹²	Maybe ^{13,14}	No
Hospital Beds ¹	Yes	Yes	Yes	Yes
Joint Braces	Yes	Yes	Yes	Yes
Orthopedic Footwear	Yes	Yes	Maybe ¹	Maybe ²
Prosthetic Devices, Other ¹	Yes	Yes	Maybe ¹	No
Respirators and Inhalators ¹⁵	Yes	Yes	Yes	Yes ¹
Resuscitators ¹⁶	Yes	Yes	Yes	Yes ¹
Spectacles	Yes	Yes	Maybe ¹⁷	No
Walking Irons ¹⁸	Yes	Yes	Yes	Yes
Wheel Chairs ¹⁹	Yes	Yes	Yes	Yes

¹When considered medically appropriate by the attending physician.

²See § 728.92(b).

³Outside the United States and at designated remote stations when considered medically appropriate by the attending physician.

⁴Contact or special lenses are not to be issued solely for cosmetic reasons. Further guidelines are contained in BUMEDINST 6810.4G.

⁵Initial issue will include, in addition to the hearing aid, one spare receiver cord, approximately 1 month's supply of batteries, and a statement indicating make, model, type of receiver, serial number, code, part numbers, "B" battery voltage, and type of "A" and "B" batteries, as appropriate. Replacement of hearing aids shall be upon the same basis as the initial issue and, except in unusual circumstances, shall not be effected within 2 years of the initial furnishing or the last replacement of the appliance.

⁶Spectacles, contact lenses, or intraocular lenses may be provided those dependents with eye conditions which require these items for complete medical or surgical management of a condition other than ordinary refractive error. For further information, consult BUMEDINST 6810.4G.

⁷May be loaned on a custody basis at the discretion of the attending physician.

⁸See subpart of this part relating to specific beneficiary.

⁹When considered by the attending physician and dentist to be an adjunct to a medical or surgical condition other than dental and when in consonance with existing legislation and directives.

¹⁰For further guidelines, consult BUMEDINST 6320.41B.

¹¹Include intraocular lenses required for implantation upon removal of cataracts.

Subpart I—Reservists—Continued Treatment, Return to Limited Duty, Separation, or Retirement for Physical Disability

§ 728.101 General.

(a) *Notice of Eligibility (NOE).* While the NOE is basically a document that substantiates entitlement to a disability benefit equal to pay and allowances, it may be accepted when required to substantiate eligibility for benefits other than pay and allowances, i.e., treatment in USMTFs under the provisions of 10 U.S.C. 6148(d).

(b) *Title 10 United States Code 6148(d).* This code states, in part, that a . . . "member of the Naval Reserve or the Marine Corps Reserve who, in time of peace, becomes ill or contracts disease in line of duty while he is on active duty or performing inactive-duty training is entitled to receive at Government expense medical, hospital, and other treatment appropriate for that illness or disease. The treatment shall be continued until the disability resulting from the illness or disease cannot be materially improved by further treatment. Such a member is also entitled to necessary transportation and subsistence incident to treatment and return to his home upon discharge from treatment."

(c) *Physical Disability Benefits.* The following, excerpted and paraphrased from SECNAVINST 1770.3, paragraph 10, is applicable when a reservist may be entitled to physical disability benefits.

(1) When a notice of eligibility (NOE) has been issued to a member hospitalized in a naval MTF and the attending physician is of the opinion that recovery is not anticipated or that the reservist is not expected to be fit for return to full duty within a reasonable period, a medical board shall be convened and the case shall be managed the same as that of a Regular member. A copy of the NOE shall accompany the medical board report forwarded to the Central Physical Evaluation Board. Disability benefits, equal to pay and allowances, shall continue in such cases until final disposition.

(2) There is no limited duty status, per se, for inactive reservists. However, if it is the opinion of the attending physician that a reservist is temporarily unfit for full duty, but will be fit for full duty following a period of convalescence or following duty with physical limitations, not to exceed 6 months, the physician may return the reservist to duty with a summary of the hospitalization or treatment. The summary shall set forth the limitations posed by the member's

disability and the period of such limitations. Followup hospitalization, treatment, and evaluation for the same condition may be provided at USMTFs during the period of restricted duty, if required. If, during the period of the restricted duty, it appears that the reservist will be permanently unfit for full duty, he or she should be promptly authorized to report for evaluation, treatment if required, and appearance before a medical board at the nearest naval MTF capable of accomplishing same. Admission to the sicklist is authorized, when required. Should the medical board recommend appearance before a physical evaluation board, disability benefits equal to pay and allowances should continue until final disposition is effected.

§ 728.102 Care from other than Federal sources.

The provisions of this subpart shall not be construed as authorizing care for reservists at other than Federal facilities or out of funds available for operation of USMTFs (supplemental care) after a period of active duty or a period of training duty ends, including travel to and from such training.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[A-5-FRL-2819-1]

Approval and Promulgation of Implementation Plans; Indiana

AGENCY: Environmental Protection Agency (USEPA).

ACTION: Final rulemaking.

SUMMARY: On March 28, 1983 Indiana submitted as a revision to its total suspended particulate (TSP) State Implementation Plan (SIP) an alternative opacity limit for the underfire stack at Bethlehem Steel Corporation's Coke Battery No. 2 in Porter County. The alternative limit is 20% opacity averaged over a 2-hour period. On March 1, 1984 (49 FR 7606), USEPA proposed to approve the limit as an equivalent visible emission limitation (EVEL) to Indiana's mass limit for this source and, today, is approving this EVEL.

EFFECTIVE DATE: This final rulemaking becomes effective on May 17, 1985.

ADDRESSES: Copies of this revision to the Indiana SIP are available for inspection at: The Office of the Federal

Register, 1100 L Street, NW., Room 8401, Washington, D.C. 20408.

Copies of the SIP revision, public comments on the notice of proposed rulemaking and other materials relating to this rulemaking are available for inspection at the following addresses: (It is recommended that you telephone Robert B. Miller, at (312) 886-6031, before visiting the Region V Office.)

Environmental Protection Agency,
Region V, Air and Radiation Branch,
230 South Dearborn Street, Chicago,
Illinois 60604

Environmental Protection Agency,
Public Information Reference Unit, 401
M Street, SW., Washington, D.C.
20460.

Indiana Air Pollution Control Division,
Indiana State Board of Health, 1330
West Michigan Street, Indianapolis,
Indiana 46206.

FOR FURTHER INFORMATION CONTACT:
Robert B. Miller, Air and Radiation
Branch (5AR-26), Environmental
Protection Agency, Region V, Chicago,
Illinois 60604, (312) 886-6031.

SUPPLEMENTARY INFORMATION: On March 28, 1983, Indiana submitted as a revision to its TSP SIP an alternative visible emission limit for the underfire stack at Bethlehem Steel Corporation's Coke Battery No. 2 in Porter County. (Porter County is designated "unclassifiable" with respect to whether the county has attained the National Ambient Air Quality Standards (NAAQS).)¹ Additional information and documentation were submitted on May 12, 1983. The proposed alternative visible emission limit would prohibit Bethlehem's Coke Battery No. 2 from emitting visible emissions in excess of 20% opacity, as averaged over a 2-hour period. The current opacity limitation is 40%.

In order to qualify for an alternative visible emission limitation, a source must conduct opacity observations simultaneously during the performance of a representative particulate mass stack test which complies with the requirements of applicable mass emission limitation.

Indiana submitted simultaneous opacity observation and stack test data from this source. The stack test data showed compliance with the applicable

¹ The primary TSP NAAQS are violated when, in a year, either: (1) The geometric mean value of monitored TSP concentrations exceeds 75 micrograms per cubic meter of air (75 µg/m³) [the annual primary standard], or (2) the maximum 24-hour concentration of TSP exceeds 260 µg/m³ more than once [the 24-hour standard]. The secondary TSP NAAQS is violated when, in a year, the maximum 24-hour concentration exceeds 150 µg/m³ more than once.

SIP mass limit contained in Indiana's particulate regulations.² In examining the stack test/opacity data developed for the Bethlehem No. 2 Coke Battery EVEL, the 2-hour 20% opacity limit is equivalent to 0.037 grains/dry standard cubic foot (gr/dscf) or to 0.076 lbs/MMBTU for this source. This is more stringent for this source than the mass emission limit currently in the SIP, and USEPA proposed to approve the 2-hour 20% alternative visible emission limit on March 1, 1984.

Only Counsel for Bethlehem Steel commented on this proposal. The comments consisted of submittal of depositions of USEPA staff, with attachments, on various subjects taken in litigation between Bethlehem and USEPA. Bethlehem did not specify what portions, if any, of these depositions are relevant to today's rulemaking. In rulemaking, the burden is on those submitting comments to articulate a position or raise an issue. In the absence of an articulated position, the rulemaker is not required to sift through documents in an attempt to ascertain their relevance. Therefore, USEPA is not responding to the submitted documents.

The 2-hour 20% opacity limit that Indiana submitted as an EVEL for the Bethlehem No. 2 Coke Oven Battery Underfire Stack is correlated to a mass emission level of 0.037 gr/dscf. Because that level is lower than the level reflected in the current underlying SIP mass emission limit, EPA approves the EVEL for so long as the current SIP mass limit applies. In the event USEPA ultimately approves a revised mass limit for this source different from the current mass limit, the 2-hour 20% opacity limit might not be equivalent to the new mass limit and thus should no longer be used to determine compliance with the mass limit. Therefore, should USEPA at any time give final approval to a new mass limit, the EVEL EPA approves today will automatically cease to be part of the

SIP. Then, unless the State submits and USEPA approves a new EVEL for the stack at the same time, the opacity limit for the stack will revert to the then applicable general Indiana opacity SIP requirements.

The Office of Management and Budget has exempted this rule from the requirements of Section 3 of Executive Order 12291.

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by (60 days from today). This action may not be challenged later in proceedings to enforce its requirements. (See 307(b)(2).)

List of Subjects in 40 CFR Part 52

Air pollution control, Incorporation by Reference, Particulate matter, Intergovernmental relations.

Note.—Incorporation by reference of the State Implementation Plan for the State of Indiana was approved by the Director of the Federal Register on July 1, 1982.

This notice is issued under authority of sections 110 and 301 of the Clean Air Act, as amended (42 U.S.C. 7410 and 7601).

Dated: April 9, 1985.

Lee M. Thomas,
Administrator.

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Indiana

Title 40 of the Code of Federal Regulations, Chapter I, Part 52 is amended as follows:

1. Section 52.770 is amended by adding new paragraph (c)(49).

§ 52.770 Identification of Plan.

(c) * * *

(49) On March 28, 1983, Indiana submitted a 20% 2-hour opacity limit as an "equivalent visible emission limit" (EVEL) for the underfire stack at Bethlehem Steel Corporation's Coke Battery No. 2 in Porter County. This EVEL is approved for as long as the SIP mass emission limit determined from 325 IAC 6-2 (October 6, 1980, submittal) for this source remains in the SIP See (c)(6), (35), and (42).

2. Section 52.776 is amended by adding new paragraph (h).

§ 52.776 Control Strategy: Particulate Matter.

(h) Equivalent Visible Emission Limits (EVEL). (1) A 20% 2-hour opacity limit for the underfire stack at Bethlehem Steel Corporation's Coke Battery No. 2 in Porter County is approved as an EVEL to determine compliance with the 325 IAC 6-2 SIP limit of 0.33 lbs/MMBTU. This EVEL is approved for as long as the SIP mass emission limit for this source remains the same as determined by 325 IAC 6-2 (October 6, 1980, submittal). See § 52.770(c)(6), (35), and (42).

[FR Doc. 85-9204 Filed 4-16-85; 8:45 am]

BILLING CODE 5560-50-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Public Land Order 6600

[ES 31023]

Michigan; Public Land Order No. 6571; Correction

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order corrects an error in Paragraph 1 of Public Land Order No. 6571 of September 17, 1984.

EFFECTIVE DATE: April 17, 1985.

FOR FURTHER INFORMATION CONTACT:

Joyce Troy, BLM Eastern States Office, 350 S. Pickett Street, Alexandria, Virginia 22304, (703)-274-0117.

By virtue of the authority vested in the Secretary of the Interior by section 204 of the Federal Land Policy and Management Act of 1976, 90 Stat. 2751; 43 U.S.C. 1714, it is ordered as follows:

In FR Doc. 84-25481 published on page 37760 in the issue of Wednesday, September 26, 1984, the third line of Paragraph 1 which reads "3,500 acres in Marquette County, is" is corrected to read "3,500 acres in Chippewa, Schoolcraft, Alger, and Delta Counties, is."

Robert N. Broadbent,
Secretary of the Interior.
April 8, 1985.

[FR Doc. 85-9199 Filed 4-16-85; 8:45 am]

BILLING CODE 4310-84-M

² The SIP mass emission limitation in 325 IAC 6-2 for this coke battery stack is 0.33 pounds per million British Thermal Units (lbs/MMBTU) (December 6, 1983, 48 FR 54599). On November 7, 1984, Indiana promulgated a new mass emission limit for the Bethlehem No. 2 Coke Battery, which is contained in 325 IAC 6-6. This mass emission limit was submitted to USEPA on December 13, 1984, and limits the Bethlehem No. 2 Coke Battery to 0.129 lb/ton of coal. This mass limit is equivalent to 0.0171 grains/dry standard cubic foot (gr/dscf), based on 1990 production. The State has not submitted a new EVEL for the Bethlehem No. 2 Coke Battery which is equivalent to 0.0171 dg/dscf. USEPA recommends that the State submit such an EVEL to be acted upon in conjunction with the revised mass limit. Nevertheless, USEPA will rulemake on the new mass emission limit by itself in future Federal Register notices.

FEDERAL COMMUNICATIONS
COMMISSION

47 CFR Part 73

[MM Docket No. 84-789; RM-4810]

TV Broadcast Stations in Anchorage,
AK

Correction

In FR Doc. 85-8093, appearing on page 13335 in the issue of Thursday, April 4, 1985, make the following correction:

The docket number in the heading, should have appeared as set forth above.

BILLING CODE 1505-01-M

47 CFR Part 73

[MM Docket No. 84-706; RM-2959; FCC 85-162]

Frequency Assignments for the
International Broadcast ServiceAGENCY: Federal Communications
Commission.

ACTION: Final rule.

SUMMARY: This action amends § 73.702(f) of the Commission's Rules by allowing international broadcast stations located in Region 3 to use the 7100-7300 kHz frequency band in addition to the bands already authorized in § 73.702(f). This action is taken to help reduce frequency congestion and increase flexibility in frequency selection for international broadcast stations.

EFFECTIVE DATE: May 16, 1985.

FOR FURTHER INFORMATION CONTACT: Charles H. Breig, Mass Media Bureau, (202) 254-3394.

SUPPLEMENTARY INFORMATION:

List of Subjects in 47 CFR Part 73

Radio Broadcasting.

Report and Order; Proceeding
Terminated

In the matter of amendment of § 73.702(f) Regarding Frequency Assignments for the International Broadcast Service; MM Docket No. 84-706, RM-2959.

Adopted: April 5, 1985.

Released: April 9, 1985.

By the Commission: Commissioner Rivera not participating.

Background

1. The Commission has before it the *Notice of Proposed Rule Making* ("Notice") 49 FR 31303 (August 6, 1984) in this proceeding and comments filed by Trans World Radio Pacific ("Trans World"), Far East Broadcasting Company, Inc. ("Far East") and The

American Radio Relay League (the "League"), as well as comments by nine amateur radio operators, and reply comments filed by Trans World and Far East.

2. The *Notice* invited comments on a proposal to amend § 73.702(f) of the Commission's Rules which sets forth the frequencies which can be used by FCC licensed international broadcast stations.¹ The proposed amendment would make it possible for stations with Region 3 locations² to use the 7100-7300 kHz band. Unlike Region 3 where such use is possible, international regulations do not permit the use of this band in the United States or elsewhere in Region 2, (the Western Hemisphere). No provision for use of this band in Region 3 was included because until recently, there were no Commission licensed stations outside of Region 2. Now that there are Commission licensed stations in Region 3, use of the 7100-7300 kHz band was proposed as a means of helping to alleviate frequency congestion.³

3. However, in making the proposal, the Commission noted that this band was allocated to the Amateur Radio Service in Region 2 and that it was in fact used for this purpose. Because of the potential for increased interference to amateur radio transmissions, the Commission raised that issue and offered an outline of a possible approach in this regard.

Comments Received

4. The comments by Trans World and Far East support the proposal and urge the Commission to adopt the rule change as proposed. They assert that the availability of this band could increase the choice of frequencies which could be used by FCC licensed stations in Region 3, while at the same time help to ease congestion in the other frequency bands allocated to international broadcasting. As to its own situation, Trans World also notes the prediction of lower sunspot numbers over the next few years. This will reduce propagation in the higher frequency bands and will require use of the lower frequency bands so that availability of the 7100-

7300 kHz band would make an important contribution to satisfying its broadcast requirements and thereby assure continued good reception in Region 3 target areas. Finally, Trans World notes that other international broadcast stations in Region 3 already have been using this band and that the only stations excluded from such use are those licensed by the Commission.

5. In contrast to this support for the proposal, the concerns of the League regarding possible interference to Region 2 radio amateurs led it to oppose the proposal unless suitable measures were included to minimize the potential for interference. To do this, the League suggests that it would be more appropriate to specify limits on the hours of frequency use rather than limit the radiation toward Region 2 as originally was suggested. This, it says, would better take into account the propagation characteristics of this band which vary with time of day, season of the year and sunspot activity. Because signals propagate better in the evening, the League urges that broadcasting in Region 3 should be prohibited between two hours before sunset at transmitting sites in Region 3 and two hours after sunrise at any location in Region 2. As to the signal levels to be radiated toward Region 2, it urges enforcement of the existing rules regarding directionalization of antennas to target areas in Region 1 or 3 (and thus away from Region 2).

6. In its reply comments, Far East suggests that if the Commission were to limit its licensees to certain hours of operation, as was urged by the League, this would open the way to other international broadcast stations not licensed by the Commission to occupy these frequencies instead. Moreover, because the Commission licenses only a small fraction of the total number of international broadcast operations, Far East doubts that the restriction proposed by the League would bring about any measurable lessening of the interference which otherwise would occur. Trans World takes a similar position and asserts that compliance with any needed restrictions could easily be ensured through the Commission's process of reviewing seasonal broadcast schedules for the stations in Region 3. In addition, Trans World states that FCC licensed international stations in Region 3 almost exclusively target their signals to the west, thereby orienting their directional antennas in a way which would avoid high signal levels toward Region 2.

¹ These are short-wave stations, operating under private auspices from locations in the United States or its territories to reception areas in foreign countries.

² Region 3 consists of the Asian/Pacific area and includes several U.S. possessions where the Commission is responsible for station licensing.

³ The stations currently authorized to operate in Region 3 are: Trans World Radio Pacific KTWR, Agana, Guam; Marcom, Inc. KYOI, Agincourt Point, Saipan; and Far East Broadcasting Company, Inc., KFBBS, Marpi, Saipan. Also Adventist Broadcasting Service, Inc. has been granted a construction permit for a station at Agat, Guam, but it has not yet gone on the air.

Discussion

7. Based on the record in this proceeding and the Commission's own experience in administering this area of its responsibilities, making the 7100-7300 kHz band available for international broadcasting could help ease the increasing congestion in the frequencies now available for such purposes. The benefits would come through two means: the stations in Region 3 would have additional frequencies available to address their needs, and to the degree to which stations in Region 3 use these newly added frequencies, the stations in Region 2 should face less congestion in the use of the other bands set aside for international broadcasting. Before proceeding to make this band available, the Commission must consider the possible impact of such a step on radio amateur operations in this band in Region 2. Amateur radio operations provide a significant service to the citizens of the United States and to people throughout the world. Their availability in times of local disasters often provide the only means of communication when normal circuits are disrupted. Their presence constitutes a valuable national resource.*

8. Because of the high transmitting powers employed by international broadcast stations as well as their use of highly directional antennas, they have a potential for causing substantial amounts of interference to radio amateur stations located in Region 2. Even though the Commission is not in a position to prevent interference caused by stations by other countries, this does not mean the Commission should ignore the substantial additional impact the FCC licensed operations could have, especially since they often operate with directional radiated power equivalent to a level of one megawatt or more. If such signal levels were directed toward Region 2, serious disruption in the use of this radio amateur band in Region 2 would result. Conversely, excessive restrictions would ignore the fact that radio amateur operations already receive interference from other Region 3 international broadcast stations, and their imposition would prevent the new band from being effectively used to accomplish its intended purpose. The

question, then, is how to balance these conflicting considerations.

9. The League would deal with this situation by precluding operation of international broadcast stations in Region 3 during (the essentially nighttime) hours when they would have the greatest potential for causing interference. Thus, for example, if average sunrise and sunset times are used and the transmitter site is assumed to be in Guam, in a worst-case situation, the station would have to be off the air as much as 16 hours per day. While this might avoid interference, such an approach would make it impossible to put the band to effective use. On the other hand, it would be equally inappropriate to permit use of the band without regard to its possible consequences for radio amateur operations. Fortunately, there is an arrangement which effectively responds to both of these concerns.

10. It is important to recognize that it is not necessary to preclude all international broadcast operations by U.S. stations in Region 3 in order to minimize interference. Interference problems arise when the broadcast operations in question would put high signal levels into locations in Region 2. This results from the orientation of the directional antenna the station uses and the hours of its operation. If the antenna is oriented directly toward a location in Region 2 and if the path to the target area is in darkness, the potential for interference is great. Conversely, if the antenna is oriented away from Region 2 and the path is in daylight, interference would not be anticipated.

11. With these aspects in mind, it is possible to fashion a rule that provides effective protection and at the same time imposes only a minimal restriction on international broadcast operations. This would involve a rule having two parts. The first would preclude having any operation at any time oriented directly toward a location in Region 2. This restriction would have virtually no effect on transmissions to target areas in Region 1 or 3. The only effect would occur in those rare instances in which the Region 3 station was oriented toward a target area to the east and thus toward Region 2. This arrangement, however, is contrary to the experience with Commission licensed Region 3 station which normally are oriented toward the west.

12. The second part of the rule would deal with the increased potential for interference during nighttime hours and the fact that high signal levels could occur in areas not directly in the signal path. Thus, during the hours of 0800 to

1600 UTC (Coordinated Universal Time) a station would be required to operate so that the radiated power would be reduced by a stated amount in azimuths toward locations in Region 2. These hours are those during which interference to radio amateurs in Region 2 would most likely occur. The amount of reduction of radiated power would be related to gain of the antenna in use. Higher-gain antennas would need a 12 dB reduction relative to the maximum power radiated in the major lobe and lower gain antennas a 6 dB reduction. This results in substantial radiated power reductions toward Region 2 during such periods operation equivalent to 1/8 and 1/4 the radiated power in the major lobe, respectively. It provides for reasonable protection at the extreme edges of Region 2, but more importantly, because FCC licensed international broadcasters are required to use highly directional antennas which have a rapid reduction (roll-off) in radiation away from the main beam, it will provide substantially greater protection within Region 2. These restrictions would result in little impact on present or future uses while avoiding what otherwise could be substantial interference. On this basis, use of the band for international broadcasting is clearly justified.

13. Accordingly, pursuant to the authority contained in section 4(i), 303, and 307(b) of the Communications Act of 1934, as amended, it is ordered that § 73.702(f) of the Commission's Rules is amended, as set forth in the attached appendix, effective May 16, 1985.

14. It is further ordered That this proceeding it terminated.

Paperwork Reduction Act

15. The proposal contained herein has been analyzed with respect to the Paperwork Reduction Act of 1980 and found to contain no new or modified form, information collection and/or record keeping, labeling, disclosure, or record retention requirements; and will not increase or decrease burden hours imposed on the public.

Regulatory Flexibility Final Analysis

1. Need for and Purpose of the Rule

The proposal was designed to increase flexibility in the choice of frequencies for Commission licensed international broadcast stations in Region 3 thereby easing congestion for continental U.S. international broadcast stations.

* Two recent Commission actions should help minimize any impact upon amateur operations resulting from international broadcasting in Region 3 in the 7100-7300 kHz band. Amateur stations near 7075-7100 kHz for telephony. See, *Second Report and Order* in PR Docket No. 82-83. Additional HF frequencies in the 12 and 30 meter bands also have been proposed. See, *Notice of Proposed Rule Making* in PR Docket No. 84-960.

II. Summary of Issues Raised by Public Comment in Response to the Initial Regulatory Flexibility Analysis, Commission Assessment, and Changes Made As a Result

A. *Issues raised.* None of the commenting parties disagreed with the Commission's assessment. However, the League did express concern about possible interference which could be caused to the Amateur Service in Region 2 and asked the Commission to impose safeguards to minimize the possibility of interference.

B. *Assessment.* The original assessment about the potential for interference was a correct one, substantiated by the record.

C. *Changes as a result.* No change was required other than those involved in selecting the means of avoiding interference.

III. Significant Alternatives Considered and Rejected

The League suggestions regarding imposing a limit on the hours of operation and engineering characteristics of these operations were used as a basis for the limitations in the rule adopted by the Commission.

18. For further information concerning this proceeding, contact Charles H. Breig, Mass Media Bureau, (202) 254-3394.

(Secs. 4, 303, 48 stat., as amended, 1066, 1082; 47 U.S.C. 154, 303)

Federal Communications Commission
William J. Tricarico,
Secretary.

Appendix

47 CFR Part 73 is amended by revising § 73.702(f) to read as follows:

§ 73.702 Assignment and use of frequencies.

(f) Frequencies assigned by the Commission shall be within the following bands which are allocated exclusively to the international broadcast service:

5,950-6,200 kHz
9,500-9,775 kHz
11,700-11,975 kHz
15,100-15,450 kHz
17,700-17,900 kHz
21,450-21,750 kHz
25,600-26,100 kHz

In addition, the following band is allocated exclusively to the international broadcast service in Region 3:

7,100-7,300 kHz.¹

The carrier frequencies assignable shall begin 5 kHz above the frequency specified above for the beginning of each band and shall be in successive steps of 5 kHz to and including 5 kHz below the frequency specified as the end of each band.

[FR Doc. 85-9248 Filed 4-16-85; 8:45 am]
BILLING CODE 6712-01-M

47 CFR Part 90

[PR Docket No. 84-414; FCC 85-95]

Interconnection of Private Land Mobile Radio Stations With the Public Switched Telephone Network in the Radio Spectrum Below 800 MHz

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission has adopted a *Part and Order* amending Part 90 of the Commission's Rules to allow greater flexibility in the interconnection of private land mobile radio stations with the public switched telephone network in the spectrum below 800 MHz.

EFFECTIVE DATE: May 2, 1985.

FOR FURTHER INFORMATION CONTACT: Nia Chirigos Cresham, Private Radio Bureau, Land Mobile and Microwave Division, Rules Branch, (202) 634-2443.

SUPPLEMENTARY INFORMATION:

List of Subjects in 47 CFR Part 90

Private land mobile radio service, Radio.

Report and Order

In the matter of amendment of Part 90 of the Commission's Rules to Prescribe Policies and Regulations to Govern the Interconnection of Private Land Mobile Radio Stations with the Public Switched Telephone Network in the Radio Spectrum below 800 MHz: PR Docket No. 84-414.

Adopted: March 1, 1985.

¹ Assignments in this frequency band will be limited to international broadcast stations located in the area designated as Region 3 by No. 395 of the International Radio Regulations and authorized only to transmit to zones and areas of reception situated outside Region 2 as defined in No. 394 of the International Radio Regulations. In addition, during the hours of 0600-1600 UTC (Coordinated Universal Time), radiation in any easterly direction that would intersect any area in Region 2 shall be limited to at least 12 dB below the maximum radiation in the major lobe for antennas with gains greater than 15 dB and at least 6 dB below the maximum radiation in the major lobe for antennas with gains of 15 dB or less.

By the Commission.
Released: March 26, 1985.

Introduction

1. On June 12, 1984, the Commission released a *Notice of Proposed Rule Making* to amend Part 90 of the Commission's rules governing how private land mobile radio stations licensed in the bands below 800 MHz might be interconnected to enable communications between the vehicles of licensees and positions in the public switched telephone network (PSTN).¹ More specifically the *Notice* proposed: (1) To allow interconnection in those cities and radio services where it is now prohibited;² (2) to permit licensees and users to share telephone service and interconnection equipment rather than to have to continue obtaining it separately; (3) to modify the requirements for special channel monitoring equipment for interconnected operations; and (4) to eliminate the rules which placed time limitations on the length of interconnected communications.³

2. The deadline for filing comments on the proposal was July 19, 1984 and the deadline for filing reply comments was August 3, 1984. Eleven comments and one reply comment were timely received.⁴ All of the comments

¹ *Notice of Proposed Rule Making*, Docket No. 84-414, 49 FR 25,255 (June 20, 1984).

² Radio transmitters licensed for operation in the Automobile Emergency, Business, Special Emergency, Special Industrial and Taxicab Radio Services may not be interconnected with the public switched telephone network within 75 miles of the nation's 25 largest urban areas. These areas are: New York, NY; Los Angeles, CA; Chicago, IL; Philadelphia, PA; Detroit, MI; San Francisco, CA; Boston, MA; Washington, DC; Cleveland, OH; St. Louis, MO; Pittsburgh, PA; Minneapolis-St. Paul, MN; Houston, TX; Baltimore, MD; Dallas, TX; Milwaukee, WI; Seattle-Everett, WA; Miami, FL; San Diego, CA; Atlanta, GA; Cincinnati, OH-KY; Kansas City, MO-KS; Buffalo, NY; Denver, CO; San Jose, CA.

³ 47 CFR 90.463 currently requires automatic monitoring equipment to be installed at the base station transmitter to prevent interference to on-going communications. This section also imposes time limitations on interconnected communications. The rule also limits initial access calls to mobile operators from the PSTN to a three second tone, after which time the transmitter closes down and no additional signals can be transmitted until a response is received from the mobile operator. In single frequency systems, interconnected conversations are limited to thirty seconds, and special equipment is installed to activate the base station receiver to monitor the frequency for a minimum of three seconds before the communication can commence. All other interconnected communications are limited to three minutes, at which time the transmitter closes down, disconnecting all circuits between the base station and the PSTN.

⁴ We received comments from the following parties: The Operating Telephone Companies

Continued

recognized that the interconnection of private land mobile radio stations with the PSTN expands significantly the communications capability of licensees and can improve the efficiency of small business operations by permitting the vehicle operator to talk to persons in the telephone network. The commenters were in favor of reducing regulatory burdens on licensees who employ interconnected systems, since this would facilitate the use of interconnection and improve effectiveness of their communications systems. However, most of the commenters expressed concern that the elimination of all of the current restrictions on the use of interconnection below 800 MHz could significantly increase congestion and interference on private radio frequencies in major cities. These commenters requested us to reconsider some aspects of the proposal in light of these concerns.

Background

3. In 1976 when the Commission began Docket No. 20846, our purpose was to develop specific rules to better define and regulate the interconnection of private land mobile radio systems with the PSTN.⁶ After receiving public comment on our proposals we completed the first phase of the proceeding by adopting rules to govern the interconnection of private land mobile radios with the PSTN in the frequency bands below 800 MHz.⁷ Our

First Report and Order adopted rules which completely barred the interconnection of private radio stations with the telephone network within 75 miles of the largest 25 cities in five service groups. (See footnote 2, *supra*.) We also placed several equipment requirements on licensees using interconnected stations below 800 MHz and set time limitations on the duration of interconnected communications. Finally, we did not allow interconnection to occur at a point common to several licensees when the radio equipment was provided by a third party.⁸

4. In 1982 we adopted a *Second Report and Order* to address the interconnection of private land mobile radios with the PSTN in the radio spectrum above 800 MHz.⁹ In that action we adopted substantially less burdensome rules for the use of interconnection by private licensees and users. For example, we did not impose any geographic restrictions as to where interconnection could occur. Instead we permitted interconnection to be employed anywhere. We also did not require special monitoring equipment to be used at the transmitter site and did not place time limitations on interconnected communications. Finally, we allowed multiple licensees and authorized users to share telephone service and interconnection equipment, as long as the telephone service was provided on a non-profit, cost-shared basis. Soon after the *Second Report and Order* was adopted, Congress enacted "The Communications Amendments Act of 1982" which addressed the interconnection of private land mobile radio transmitters with the PSTN.¹⁰ The new legislation was applied in 1983 by our *Memorandum Opinion and Order* which affirmed our actions regarding interconnection in the bands above 800 MHz.¹¹ We also further liberalized our rules on interconnection above 800 MHz in conformance with the new legislation. We made no changes, however, to the rules in the *First Report and Order* governing interconnection in the bands below 800 MHz.

5. In this current phase of our interconnect proceedings, our objective is to review the restrictions we imposed on interconnection below 800 MHz in 1978 and to see if technical developments during the past six years

warrant relaxation of our rules. Of particular concern are those restrictions which ban completely the use of interconnection within 75 miles of the 25 largest cities, prohibit common point interconnection, and impose special monitoring equipment and time limitations on interconnected communications below 800 MHz.¹² We proposed the elimination of these restrictions in our *Notice* in order to reduce the burdens on licensees seeking to employ interconnected communications. We recognized, however, that most of the channels below 800 MHz are shared channels and we were aware that increased channel congestion due to longer transmission times could result from an increase in the number of interconnected transmitters. However, we felt that this problem could be controlled through mutual cooperation and coordination among licensees, particularly since our rules give us broad discretion to impose solutions on a case-by-case basis should cooperation fail.¹³ We also proposed to make the use of interconnection secondary to dispatch operations in order to assure the primacy of dispatching. This method has proven to be successful for the bands above 800 MHz.

Decision

6. After extensive consideration of the comments, we have determined to modify and to eliminate several of our rules governing interconnection of private land mobile radio stations with the PSTN in the bands below 800 MHz. We are modifying the absolute ban on interconnection in the five specified services within 75 miles of the 25 largest cities to allow interconnection within 75 miles of these cities in the five services, if a licensee has obtained the consent of all co-channel licensees located both (1) Within 75 miles of the center of the city; and (2) within 75 miles of the interconnected base station transmitter. More specifically, consent is required of all co-channel licensees located within the intersection of the following two circles: (1) A circle with a radius of 75 miles around the center of the city; and (2) a circle with a radius 75 miles around the interconnected base station transmitter. We are also eliminating the prohibition on common point interconnection and will allow multiple licensees and authorized users to interconnect at a common point as long as the telephone service is provided on a non-profit, cost-shared basis. We are

⁶ IOTC's; Pennzoil Company (Pennzoil); Utilities Telecommunications Council (UTC); Special Industrial Radio Service Association, Inc. (SIRSA); Central Committee on Telecommunications of the American Petroleum Institute (API); Motorola, Inc. (Motorola); General Electric Company (GE); National Association of Business and Educational Radio (NABER); Association of American Railroads (AAR); Dallas County Hospital District (Dallas County). We received reply comments from UTC.

⁷ Comments were also received by Telocator Network of America (Telocator). Telocator asserts that the rule and policy changes at issue are in conflict with the "The Communications Amendments Act of 1982," Pub. L. 97-259, 96 Stat. 1087, September 13, 1982; See section 120 (Section 331 of the Communications Act of 1934, as amended, is codified at 47 U.S.C. 332). Telocator did not argue the issues *de novo*, but incorporated by reference its Petition for Reconsideration in Docket No. 20846, filed on July 28, 1983. The arguments raised by Telocator in its comments were considered and addressed in our *Memorandum Opinion and Order*, Docket No. 20846, 49 FR 26,066 (June 26, 1984). Telocator has not raised any new issues to be considered at this time. The *Memorandum Opinion and Order* has been appealed to the United States Court of Appeals, District of Columbia Circuit, *Telocator Network of America v. FCC & USA*, No. 83-1905.

⁸ *Notice of Inquiry and Notice of Proposed Rule Making*, Docket No. 20846, 41 FR 28540 (July 12, 1976).

⁹ *First Report and Order*, Docket No. 20846, 69 FCC 2d 1831 (1978); 43 FR 38306 (August 2, 1978).

¹⁰ See 47 CFR 90.477(d)(1), (3) and 90.483.

¹¹ *Second Report and Order*, Docket No. 20846, 69 FCC 2d 741 (1982).

¹² *The Communications Amendments Act of 1982*, *supra* at section 331, 47 U.S.C. 332.

¹³ *Memorandum Opinion and Order*, Docket No. 20846, 48 FR 29512 (June 27, 1983).

¹⁴ 47 CFR 90.477(d)(1), (3) and 90.483.

¹⁵ See 47 CFR 90.173.

modifying the time limitations and the special equipment requirements to allow licensees to operate without these restrictions if they have obtained the consent of co-channel licensees located within a 75 miles radius of the interconnected base station transmitter.

Discussion

75 Mile Rule

7. Our rules currently prohibit any interconnection in the Automobile Emergency, Business, Special Emergency, Special Industrial, and Taxicab Radio Services within 75 miles of the 25 cities listed in footnote 2, *supra*, and in § 90.477(d)(3). The initial purpose of this rule was to prevent further congestion on shared channels in highly populated areas. Our concern was that typical telephone conversions tend to last longer than typical dispatch transmissions. It does, however, deny a significant communications capability to a larger number of licensees. We proposed to eliminate the rule in order to enable licensees to make greater and more effective use of their communications systems by enabling them to talk from their vehicles to positions in the public switched telephone network, and vice versa, thereby generally improving their communications capability and the overall quality of service to the public. We proposed to accomplish this by making interconnected communications secondary to dispatch and by allowing co-channel licensees to coordinate among themselves the operation of interconnected transmitter to avoid interference.

8. Most of the commenters favored the retention of the geographic restrictions on the use of interconnection within 75 miles of the nation's 25 largest cities. The major concern of those who wished to retain the rule was the amount of congestion which already exists in the major urban areas. NABER, AAR, Motorola, SIRSA, and API argued that the vast majority of stations operating below 800 MHz share frequencies, and that licensees below 800 MHz do not receive the co-channel separation protection that licensees receive above 800 MHz. AAR stated that there are too many licensees below 800 MHz to achieve any kind of cooperation, particularly since channels are often shared by diverse users. The OTC's Pennzoil, GE, and Dallas County, however, favored the elimination of the rule. GE felt that the liberalization of the rules would increase system efficiency. GE also pointed out that the cost of air time for the licensees of shared transmitters such as "community

repeaters" would deter the excessive use of interconnection. Motorola proposed that the rule be retained only in the Business Radio Service and that it be eliminated in the other private radio services. API proposed that the Commission allow interconnection in urban areas, but strictly enforce the time, signal, and equipment limitations contained in Section 90.483.

9. After weighing the concerns, we believe a middle course is possible which will permit interconnection where feasible, but which will assure that excessive interference to dispatch systems will not occur. This approach will permit co-channel users to decide for themselves whether or not their particular operating environment will support interconnection. If all of the co-channel users can agree to permitting interconnection, it will be allowed; if they cannot it will not be allowed. Thus, we are modifying this rule to allow licensees in these five services to interconnect within 75 miles of the 25 cities if they have obtained the consent of all co-channel licensees located both (1) within 75 miles of the center of the city; and (2) within 75 miles of the interconnected base station transmitter. More specifically, consent is required of all co-channel licensees located within the intersection of the following two circles: (1) A circle with a radius of 75 miles around the center of the city; and (2) a circle with a radius of 75 miles around the interconnected base station transmitter. The consensual agreements among the co-channel licensees must specifically state the terms agreed upon and a statement must be submitted to the Commission indicating that co-channel licensees have consented to the use of interconnection. Interconnection, however, would continue to be subordinate to dispatch operations. If a licensee has agreed to the use of interconnection on the channel, but later decides against the use of interconnection, the licensee may request that the co-channel licensees reconsider the use of interconnection. If the licensee is unable to reach an agreement with co-channel licensees, the licensee may request that the Commission consider the matter and assign it to another channel. Frequency coordinators currently consider the compatibility of co-channel licensees' radio systems prior to recommending a frequency assignment to the Commission. In recommending frequencies for applicants, frequency coordinators should consider whether an applicant proposes to interconnect its radio system and would be compatible with interconnected co-channel

licensees.¹⁴ However, if a new licensee is assigned to a frequency where all the co-channel licensees have agreed to the use of interconnection and the new licensee does not agree, the new licensee may request that the co-channel licensees reconsider the use of interconnection. If the new licensee cannot reach an agreement with co-channel licensees, it may request that the Commission reassign it to another channel. Such an approach, we are persuaded, will give licensees maximum flexibility in the operation of their systems, while at the same time assuring that interconnection does not impair the operation of dispatch systems.

Restriction on Common Point Interconnection

10. Our current rules prohibit interconnection at a common point when the radio equipment is provided by a third party, except where the third party involvement is limited to the sale or lease of radio equipment and incidental maintenance, and the station and the telephone service are cost-shared on a non-profit basis with costs prorated among the users.¹⁵ In 1978, we specifically deferred the adoption of new rules allowing interconnection at a common point pending resolution of the regulatory status of third party arrangements.¹⁶ Since that time we have allowed the sharing of private land mobile transmitters and the third party provision of radio equipment.¹⁷ We have also allowed third parties, including Specialized Mobile Radio Service licensees, to act as agents in obtaining telephone service for other licensees or users above 800 MHz, as long as the telephone service is provided on a non-profit, non-resale basis in conformance with "The Communications Amendments Act of 1982." Further, we have determined that the interconnection device or "patch" is an unlicensed piece of electronic gear widely manufactured and available from many sources and that there is no public interest reason for regulating the manner in which it is obtained.¹⁸ We proposed,

¹⁴ See Frequency Coordination in the Private Land Mobile Radio Services, *Notice of Proposed Rule Making*, Docket No. 83-737, 49 FR 45454 (November 16, 1984).

¹⁵ 47 CFR 90.477(d)(1).

¹⁶ *First Report and Order*, *supra* at paragraph 47.

¹⁷ *Report and Order*, Docket No. 18921, 47 FR 19527 (May 6, 1982); *Memorandum Opinion and Order on Reconsideration*, Docket No. 18921, 48 FR 26621 (June 9, 1983).

¹⁸ *Memorandum Opinion and Order*, Docket No. 20846, *supra*.

therefore, to allow common point interconnection below 800 MHz as we had already done above 800 MHz, and to allow third parties to act as ordering agents as long as telephone service is obtained from an authorized provider and shared on a non-profit basis.

11. The comments unanimously favored the elimination of this rule as long as the telephone service is cost-shared on a non-profit basis. Motorola and Pennzoil both indicated that this action would provide significant savings to licensees and improve the quality of service. We agree. The effect of the current rule is inefficient because it denies private radio licensees and users below 800 MHz the ability to share telephone service on a non-profit basis and to share interconnection equipment. Accordingly, we will eliminate this rule and allow interconnection to be accomplished at any location through a separate or shared interconnection device. When land stations are multiple licensed or shared by authorized users, we will allow arrangements for the telephone service to be made with a duly authorized carrier by users, licensees, or their authorized agents on a non-profit, cost-shared basis.

Equipment and Time Restrictions

12. Section 90.483 of our rules provides that when a frequency is shared by more than one station each licensee must install automatic monitoring equipment at the base station to prevent the activation of the transmitter when communications are in progress.

13. Section 90.483 of our rules also contains specific time limitations on the duration of interconnected communications. Calls to mobile operators from points in the PSTN are limited to the transmission of a three second tone, after which time the transmitter automatically closes down. No additional signals can be transmitted until a response from the mobile operator is received. In single frequency systems, special equipment must be installed to limit any single transmission from the PSTN to thirty seconds. In all other systems transmitters must have a timer installed to limit interconnected communications to three minutes. After the three minutes, the transmitter must close down, disconnecting all circuits between the base station and the PSTN. The purpose of the time limitations is to limit the length of interconnected calls in order to minimize the likelihood of channel congestion.

14. In order to comply with the requirements of Section 90.483, licensees are required to install equipment at the base station transmitter which automatically monitors the frequencies

and closes down the transmitter at the end of the allotted time for communications. Even where there is a single licensee on the channel, the licensee must still install this monitoring equipment under the current rule. We proposed to eliminate these requirements in order to allow licensees to reduce their equipment expenses and to facilitate interconnected communications.

15. The majority of the comments favored the retention of our rule requiring special monitoring equipment and time limitations for interconnection below 800 MHz. UTC, SIRSA, AAR, and Motorola wanted to retain these rules because they did not feel that our proposal to allow interconnection only on a secondary basis would be sufficient to prevent increased channel congestion and interrupted communications. API proposed to retain these rules for only the 25 largest cities. NABER favored the elimination of the time restrictions and stated that monitoring equipment was not necessary in all instances. The OTC's, Pennzoil, GE, and Dallas County favored the elimination of the rules.

16. We are aware of the congestion problems that exist on shared channels and that, absent our rules, it might be difficult to coordinate reasonable time limits on interconnected communications on channels often shared by users with diverse or competing interests. Due to the large number of licensees on most private radio channels, we must make every attempt to minimize congestion and interference. On the other hand, our current rules place these burdens on licensees whether or not there are co-channel users in the area. After considering this matter, we conclude in situations in which there are no other licensees on a frequency within a given geographic area, there is no need to require licensees to install monitoring equipment *ab initio*. We will allow co-channel licensees to decide whether to use monitoring equipment. We will also allow co-channel licensees to decide whether to use the Commission's time limitations, or to set their own time limitations, or to use no time limitations. We will dispense with these requirements where there are multiple licensees on the channel if they have obtained the consent of all co-channel licensees located within a 75 mile radius of the interconnected base station transmitter. The consensual agreements among the co-channel licensees must specifically state the terms agreed upon and a statement must be submitted to the Commission indicating that all co-channel licensees have consented to the

use of interconnection. If a licensee has agreed that the use of monitoring equipment is not necessary, but later decides that the monitoring equipment is necessary, the licensee may request that the co-channel licensees reconsider the use of monitoring equipment. If the licensee cannot reach an agreement with co-channel licensees, the licensee may request that the Commission consider the matter and assign it to another channel. If a new licensee is assigned to a frequency where all the co-channel licensees have agreed that the use of monitoring equipment is not necessary, and the new licensee does not agree, the new licensee may request the co-channel licensees to reconsider the use of monitoring equipment. If the new licensee cannot reach an agreement with the co-channel licensees, it should request a new channel from the Commission. This approach will allow licensees maximum flexibility in the operation of their systems and encourage cooperation among co-channel licensees.

17. All of the comments endorsed the editorial amendments we proposed in the *Notice*. Therefore, we will adopt the new definition of interconnection to conform to the language contained in "The Communications Amendments Act of 1982", *supra*. We will also amend and clarify our rule on the use of interconnection on the offset frequencies.¹⁹ A number of comments requested that we further amend our rules on paging operations to allow paging signals to be transmitted from telephone positions in the PSTN in all private radio bands as we have allowed in the 929-930 MHz band.²⁰ Our *Notice* did not discuss such an amendment and we did not request comments on this issue. We, therefore, will not address such an amendment in this proceeding.

Final Regulatory Flexibility Analysis

The Objectives

18. The Commission seeks to promote rapid and efficient communications and encourage larger and more effective use of the radio by enhancing the ability of small and large businesses to employ interconnection in their private communications systems in furtherance of the public interest.

Description, Potential Impact and Number of Small Entities Affected

19. This action may impact both small and large businesses, licensees, and users since it will allow for more liberal

¹⁹ 47 CFR 90.7 and 90.476.

²⁰ 47 CFR 90.490 (c) and (d).

use of interconnection between private land mobile radio stations licensed to operate below 800 MHz with the PSTN. We did not receive any comments from interested parties on this particular issue. We did receive comments which indicated some concern that the total elimination of restrictions on interconnection would cause increased congestion on the channels below 800 MHz. Therefore, we adopted an approach which allows licensees to choose whether or not to implement these restrictions. Since private radio communications which are interconnected with the PSTN may be longer than typical dispatch communications, the channels may be more congested than they would be in the absence of interconnection. However, the possibility of increased channel congestion must be balanced against the increased flexibility private licensees will have in meeting their communications needs. This action will give licensees the opportunity to cooperate in the use of their communications systems in order to increase their service options.

*Any Significant Alternatives
Minimizing the Impact on Small Entities
and Consistent With the Stated
Objectives*

20. None.

Paperwork Reduction Act Statement

21. The decision contained herein has been analyzed with respect to the Paperwork Reduction Act of 1980 and found to contain no new or modified form, information collection and/or recordkeeping, labeling, disclosure or record retention requirements, and will not increase or decrease burden hours imposed on the public.

22. Accordingly, it is ordered, that effective May 2, 1985, Part 90 of the Commission's Rules, 47 CFR Part 90, is amended as set forth in the attached Appendix and that this proceeding is terminated. Authority for this action is found in sections 4(i) and 303 of the Communications Act of 1934, as amended, 47 U.S.C. § 154(i) and 303.

23. For further information on this proceeding contact Nia Chirigos Cresham, Rules Branch, Land Mobile and Microwave Division, Private Radio Bureau, Federal Communications Commission, Washington, D.C. 20554.

(Secs. 4, 303, 48 stat., as amended, 1066, 1082; 47 U.S.C. 154, 303)

Federal Communications Commission.
William Tricarico,
Secretary.

Appendix

**PART 90—PRIVATE LAND MOBILE
RADIO SERVICES**

Part 90 of Chapter I of Title 47 of the Code of Federal Regulations is amended as follows:

1. Section 90.7 is amended by revising the definition for "Interconnection" to read as follows:

§ 90.7 Definitions.

Interconnection. Connection through automatic or manual means of private land mobile radio stations with the facilities of the public switched telephone network to permit the transmission of messages or signals between points in the wireline or radio network of a public telephone company and persons served by private land mobile radio stations. Wireline or radio circuits or links furnished by common carriers, which are used by licensees or other authorized persons for transmitter control (including dial-up transmitter control circuits) or as an integral part of an authorized, private, internal system of communication or as an integral part of dispatch point circuits in a private land mobile radio station are not considered to be interconnection for purposes of this rule part.

2. Section 90.476 is revised to read as follows:

§ 90.476 Interconnection of fixed stations and certain mobile stations.

(a) Fixed stations and mobile stations used to provide the functions of fixed stations pursuant to the provisions of paragraphs (c)(4) and (c)(36) of § 90.75 and § 90.267 are not subject to the interconnection provisions of § 90.477 and § 90.483 and may be interconnected with the facilities of common carriers.

(b) Mobile stations used to provide the functions of base and mobile relay stations pursuant to the provisions of paragraphs (c)(4) and (c)(36) of § 90.75 and § 90.267 are not subject to the provisions of paragraph (d)(3) of § 90.477 and may be interconnected with the facilities of common carriers subject to the provisions of paragraph (d)(1), (d)(2) and (e) of § 90.477 and § 90.483.

3. Section 90.477, paragraphs (b)(1) and (d)(1) through (d)(3) are revised to read as follows:

§ 90.477 Interconnected System.

(b) * * *

(1) Interconnected operation is on a secondary basis to dispatch operation. This restriction will not apply to trunked systems or on any channel assigned exclusively to one licensee.

(d) * * *

(1) Interconnected operation is on a secondary basis to dispatch operation. This restriction will not apply to trunked systems or on any channel assigned exclusively to one licensee.

(2) Interconnection may be accomplished at any location through a separate or shared interconnection device. When land stations subject to this part are multiple licensed or shared by authorized users, arrangements for telephone service must be made with a duly authorized carrier by users, licensees, or their authorized agents on a non-profit cost sharing basis. When telephone service costs are shared, at least one licensee participating in the cost sharing arrangement must maintain cost sharing records and the costs must be distributed at least once a year. Licensees, users, or their authorized agents may also make joint use arrangements with a duly authorized carrier and arrange that each licensee or user pay the carrier directly for the licensee's or user's share of the joint use of the shared telephone service. A report of the cost distribution must be placed in the licensee's station records and made available to participants in the sharing and the Commission upon request. In all cases, arrangements with the duly authorized carrier must disclose the number of licensees and users and the nature of the use.

(3) In the Special Emergency Radio Service (Subpart C of this part), except for medical emergency systems in the 450-470 MHz band, the Business and Special Industrial Radio Services (Subpart D of this part), and the Automobile Emergency and Taxicab Radio Services (Subpart E of this part), interconnection will be permitted only where the base station site or sites of proposed stations are located 75 miles or more from the designated centers of the urbanized areas listed below. If licensees seek to interconnect in these five services within 75 miles of the 25 cities they must obtain the consent of all co-channel licensees located both within 75 miles of the center of the city; and within 75 miles of the interconnected base station transmitter. The consensual agreements among the co-channel licensees must specifically state the terms agreed upon and a statement must be submitted to the Commission indicating that all co-channel licensees have consented to the use of

interconnection. If a licensee has agreed to the use of interconnection on the channel, but later decides against the use of interconnection, the licensee may request that the co-channel licensees reconsider the use of interconnection. If the licensee is unable to reach an agreement with co-channel licensees, the licensee may request that the Commission consider the matter and assign it to another channel. If a new licensee is assigned to a frequency where all the co-channel licensees have agreed to the use of interconnection and the new licensee does not agree, the new licensee may request that the co-channel licensees reconsider the use of interconnection. If the new licensee cannot reach an agreement with co-channel licensees it may request that the Commission reassign it to another channel.

Urbanized area	North latitude	West longitude
New York, N.Y. northeastern N.J.	40°45'08"	73°59'38"
Los Angeles-Long Beach, Calif.	34°03'15"	118°14'28"
Chicago, Ill.	41°52'28"	87°38'22"
Philadelphia, Pa.-New Jersey	39°56'58"	75°09'21"
Detroit, Mich.	42°19'48"	83°02'57"
San Francisco-Oakland, Calif.	37°46'39"	122°24'40"
Boston, Mass.	42°21'24"	71°03'25"
Washington, D.C.-Maryland-Virginia	38°53'51"	77°00'33"
Cleveland, Ohio	41°29'51"	81°41'50"
St. Louis, Mo.-Illinois	38°37'45"	90°12'22"
Pittsburgh, Pa.	40°26'19"	80°00'00"
Minneapolis-St. Paul, Minn.	44°58'57"	93°15'43"
Houston, Tex.	29°45'26"	95°21'37"
Baltimore, Md.	39°17'26"	76°36'45"
Dallas, Tex.	32°47'09"	96°47'37"
Milwaukee, Wis.	43°02'19"	87°54'15"
Seattle-Everett, Wash.	47°36'32"	122°20'12"
Miami, Fla.	25°46'37"	80°11'32"
San Diego, Calif.	32°42'53"	117°09'21"
Atlanta, Ga.	33°45'10"	84°23'37"
Cincinnati, Ohio-Kentucky	39°06'07"	84°30'35"
Kansas City, Mo.-Kansas	39°04'56"	94°35'20"
Buffalo, N.Y.	42°52'52"	78°52'21"
Denver, Colo.	39°44'58"	104°59'22"
San Jose, Calif.	37°20'16"	121°53'24"

4. Section 90.483, paragraphs (b)(1)(ii), (b)(2)(i), (b)(2)(ii), (c), and (d) are revised to read as follows:

§ 90.483 Permissible methods and requirements of interconnecting private and public systems of communications.

(b) * * *

(1) * * *

(ii) When a frequency is shared by more than one system, automatic monitoring equipment must be installed at the base station to prevent activation of the transmitter when signals of co-channel stations are present and activation would interfere with communications in progress. Licensees may operate without the monitoring equipment if they have obtained the consent of all co-channel licensees located within a 75 mile radius of the interconnected base station transmitter.

A statement must be submitted to the Commission indicating that all co-channel licensees have consented to operate without the monitoring equipment. If a licensee has agreed that the use of monitoring equipment is not necessary, but later decides that the monitoring equipment is necessary, the licensee may request that the co-channel licensees reconsider the use of monitoring equipment. If the licensee cannot reach an agreement with co-channel licensees, the licensee may request that the Commission consider the matter and assign it to another channel. If a new licensee is assigned to a frequency where all the co-channel licensees have agreed that the use of monitoring equipment is not necessary, and the new licensee does not agree, the new licensee may request the co-channel licensees to reconsider the use of monitoring equipment. If the new licensee cannot reach an agreement with co-channel licensees, it should request a new channel from the Commission. Systems on frequencies above 800 MHz are exempt from this requirement.

(2) * * *

(i) When a frequency is shared by more than one system, automatic monitoring equipment must be installed at each base station to prevent its activation when signals of other co-channel stations are present and activation would interfere with communications in progress. Licensees may operate without this equipment if they have obtained the consent of all co-channel licensees located within a 75 mile radius of the interconnected base station transmitter. A statement must be submitted to the Commission indicating that all co-channel licensees have consented to operate without the monitoring equipment. If a licensee has agreed that the use of monitoring equipment is not necessary, but later decides that the monitoring equipment is necessary, the licensee may request that the co-channel licensees reconsider the use of monitoring equipment. If the licensee cannot reach an agreement with co-channel licensees, the licensee may request that the Commission consider the matter and assign it to another channel. If a new licensee is assigned to a frequency where all the co-channel licensees have agreed that the use of monitoring equipment is not necessary, and the new licensee does not agree, the new licensee may request the co-channel licensees to reconsider the use of monitoring equipment. If the new licensee cannot reach an agreement with co-channel licensees, it should request a new channel from the

Commission. Systems above 800 MHz are exempt from this requirement.

(ii) Initial access from points within the public switched telephone network must be limited to transmission of a 3 second tone, after which time the transmitter shall close down. No additional signals may be transmitted until acknowledgement from a mobile station of the licensee is received. Licensees are exempt from this requirement if they have obtained the consent of all co-channel licensees located within a 75 mile radius of the interconnected base station transmitter. However, licensees may choose to set their own time limitations. A statement must be submitted to the Commission indicating that all co-channel licensees have consented to operate without the monitoring equipment. If a licensee has agreed that the use of monitoring equipment is not necessary, but later decides that the monitoring equipment is necessary, the licensee may request that the co-channel licensees reconsider the use of monitoring equipment. If the licensee cannot reach an agreement with co-channel licensees, the licensee may request that the Commission consider the matter and assign it to another channel. If a new licensee is assigned to a frequency where all the co-channel licensees have agreed that the use of monitoring equipment is not necessary, and the new licensee does not agree, the new licensee may request the co-channel licensees to reconsider the use of monitoring equipment. If the new licensee cannot reach an agreement with co-channel licensees, it should request a new channel from the Commission. Systems above 800 MHz are exempt from this requirement.

(c) In single frequency systems, equipment must be installed at the base station which will limit any single transmission from within the public switched telephone network to 30 seconds duration and which in turn will activate the base station receiver to monitor the frequency for a period of not less than three (3) seconds. The mobile station must be capable of terminating the communications during the three (3) seconds. Licensees are exempt from this requirement if they have obtained the consent of all co-channel licensees located within a 75 mile radius of the interconnected base station transmitter. However, licensees may choose to set their own time limitations. A statement must be submitted to the Commission indicating that all co-channel licensees have consented to operate without the monitoring equipment. If a licensee has agreed that the use of monitoring equipment is not necessary, but later

decides that the monitoring equipment is necessary, the licensee may request that the co-channel licensees reconsider the use of monitoring equipment. If the licensee cannot reach an agreement with co-channel licensees, the licensee may request that the Commission consider the matter and assign it to another channel. If a new licensee is assigned to a frequency where all the co-channel licensees have agreed that the use of monitoring equipment is not necessary, and the new licensee does not agree, the new licensee may request the co-channel licensees to reconsider the use of monitoring equipment. If the new licensee cannot reach an agreement with co-channel licensees, it should request a new channel from the Commission.

(d) A timer must be installed at the base station transmitter which limits communications to three (3) minutes. After three (3) minutes, the system must close down, with all circuits between the base station and the public switch telephone network disconnected. This provision does not apply to systems licensed in the Police, Fire, Local Government, Special Emergency, Power, Petroleum, Railroad Radio Services, or above 800 MHz. All systems must be equipped with a timer that closes down the transmitter within three minutes of the last transmission. Licensees may operate without these requirements if they have obtained the consent of all co-channel licensees located within a 75 mile radius of the interconnected base station transmitter. However, licensees may choose to set their own time limitations. A statement must be submitted to the Commission indicating that all co-channel licensees have consented to operate without the monitoring equipment. If a licensee has agreed that the use of monitoring equipment is not necessary, but later decides that the monitoring equipment is necessary, the licensee may request that the co-channel licensees reconsider the use of monitoring equipment. If the licensee cannot reach an agreement with co-channel licensees, the licensee may request that the Commission consider the matter and assign it to another channel. If a new licensee is assigned to a frequency where all the co-channel licensees have agreed that the use of monitoring equipment is not necessary, and the new licensee does not agree, the new licensee may request the co-channel licensees to reconsider the use of monitoring equipment. If the new licensee cannot reach an agreement with co-channel licensees, it should request a new channel from the Commission.

[FR Doc. 84-9249 Filed 4-16-84; 8:45 am]

BILLING CODE 6712-01-M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. 74-09; Notice 16]

Child Restraint Systems for Use in Motor Vehicles and Aircraft

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Final rule.

SUMMARY: This rule amends the inversion test added Standard No. 213, *Child Restraint Systems*, to allow those manufacturers which choose to do so to certify their restraints for use in both motor vehicles and aircraft. These amendments specify more objective criteria for the testing procedures and determining compliance with the inversion tests. This rule adopts what was proposed, except that the rate of acceleration and deceleration at the start and finish of the test is now specified. The rule also specifically allows manufacturers the option of using any of the specified aircraft seats and safety belts. In addition, several typographical errors have been corrected.

EFFECTIVE DATE: This rule becomes effective April 17, 1985.

ADDRESS: Petitions for reconsideration may be submitted within 30 days after publication of this rule in the *Federal Register* to: Administrator, NHTSA, 400 Seventh Street, S.W., Washington, D.C. 20590.

FOR FURTHER INFORMATION CONTACT: Mr. Vladislav Radovich, Office of Vehicle Safety Standards, NRM-12, National Highway Traffic Safety Administration, 400 Seventh Street, S.W., Washington, D.C. 20590 (202-426-2264).

SUPPLEMENTARY INFORMATION: During the latter half of 1982, the Department of Transportation had two standards for child restraints. Child restraints for use in motor vehicles had to be certified as complying with the requirements of this agency's Standard No. 213 (49 CFR 571.213). That standard specifies performance and labeling requirements applicable to child restraints. Child restraints for use in aircraft had to be certified as complying with the requirements of the Federal Aviation Administration's (FAA) Technical Standard Order C100. That standard required child restraints to satisfy differing performance and labeling requirements if they were to be used in aircraft.

The result of these differing requirements was that only a few of the child restraints certified for use in motor vehicles were also certified for use in aircraft. In early 1983, the National Transportation Safety Board considered the safety problems posed for young children traveling in motor vehicles and aircraft and urged that a variety of actions be taken to promote increased use of child restraints. One of those recommendations was that the Department of Transportation simplify its two different standards setting forth requirements for child restraints, by combining the standards into a single standard.

After considering the benefits which would result from the increased use of child restraints, the FAA and NHTSA jointly concluded that the process of certifying child restraints for use in both motor vehicles and aircraft could and should be simplified and expedited. By combining the separate NHTSA and FAA standards into a single standard under the jurisdiction of a single agency, child restraint manufacturers could avoid the difficulties of dealing with different standards, methods of certification, and test procedures promulgated by the two different agencies. Accordingly, a notice of proposed rulemaking (NPRM) was published at 48 FR 36849, August 15, 1983.

This notice proposed that NHTSA would be the sole agency responsible for administering the new Standard No. 213, which would be applicable to both child restraints designed for use in motor vehicles and child restraints designed for use in aircraft. In essence, the notice proposed that the requirements in both agencies' standards be adopted *in toto* and simply combined in an expanded version of Standard No. 213. This would eliminate the problems inherent in dealing with the differing certification and testing procedures of the two agencies and consolidate all the requirements into one standard.

After publication of the NPRM, NHTSA and FAA undertook a joint testing program of all 42 models of child restraints being manufactured at that time and certified as complying with the requirements of Standard No. 213. The purpose of the joint testing program was to determine whether these child restraints could also be certified as complying with the FAA standard for child restraints for use in aircraft. The joint testing program showed that some of the FAA requirements proposed to be added to Standard No. 213 were simply less severe tests of performance capabilities which had already been

measured in testing to satisfy the NHTSA requirements. Hence, those requirements were deemed redundant and not necessary to ensure adequate protection of restraint occupants in aircraft.

NHTSA published a final rule amending Standard No. 213 at 49 FR 34357, August 30, 1984. That rule added one additional test to Standard No. 213 which had to be satisfied by those child restraint manufacturers which chose to certify their products for use in both motor vehicles and aircraft. The additional test was an inversion test, whose purpose is to ensure that child restraints certified for use in aircraft adequately protect occupants against the dangers posed by sudden air turbulence. The procedures to be followed were adopted exactly as proposed in the NPRM, which was in turn drawn verbatim from the FAA standard.

A number of the comments received in response to the NPRM agreed with the proposal to include an inversion test in Standard No. 213, but questioned the "vagueness and subjectivity" associated with the inversion test as proposed. After reviewing both the proposed criteria and the comments received on that proposal, NHTSA concluded that the test procedure should be clarified. However, the rulemaking procedures of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) precluded the agency from adopting the modifications to the test procedure in the final rule. This was because 5 U.S.C. 553 requires that interested persons receive notice of proposed rulemaking, and that such notice shall include either the terms or substance of the proposed rule or a description of the subjects and issues involved. The NPRM did not give the public notice that NHTSA was even considering different criteria than those which were proposed, so the final rule could not adopt such criteria.

To correct this perceived shortcoming of the final rule, NHTSA published another NPRM on the same day as the final rule, at 49 FR 34374, August 30, 1984. That notice proposed to establish the procedures and criteria used by NHTSA and the FAA in the joint testing program as the procedures and criteria to be followed in the inversion test just added to Standard No. 213. Only one commenter responded to this NPRM.

This notice proposed that, to prepare for the inversion test, the subject child restraint should be attached to a representative aircraft passenger seat using only an FAA-approved aircraft safety belt and FAA-approved aircraft safety belt extensions, if needed. A representative aircraft passenger seat

was defined as either an FAA-approved production aircraft passenger seat or a simulated aircraft passenger seat conforming to Figure 6.

The commenter stated that this procedure failed to specify objective criteria, as required by section 102(2) of the National Traffic and Motor Vehicle Safety Act (15 U.S.C. 1391(2)), because it was not clear that every FAA-approved production passenger seat is the equivalent of the simulated passenger seat shown in Figure 6. In the same vein, the commenter argued that it was not clear that all FAA-approved safety belts and safety belt extensions were equivalent for the purposes of the inversion test. If they are not equivalent, the commenter argued, the outcome of the inversion test would depend on the particular seat and/or safety belt chosen for the tests. When the outcome of the test is influenced by something other than the properties of what is being tested, the test is not objective. To remedy this, the commenter urged that the inversion test be amended to either specify the exact seat and safety belt combinations which would be used for testing or specify that the seat and safety belts may be chosen at the manufacturer's option from among any of the specified seats and safety belts.

The inversion test in Standard No. 213 is a qualitative test, the results of which are mainly dependent upon the geometry of the aircraft seat and safety belt combination. The test results will not be significantly affected by the seat's structural and padding characteristics or by the seat belt properties. Nevertheless, the commenter is correct in asserting that the properties of the particular aircraft seat and safety belt used in a test *might* make the difference between the restraint passing and failing the test in a very marginal case. The agency wishes to emphasize that this is a possibility, but it has not been demonstrated. In the joint testing program in which all currently produced models of child restraints were tested, all restraints passed the inversion test, using the criteria adopted in this rule.

To address this possibility, the rule adopts the commenter's suggestion that the proposed language be amended to specify that child restraint manufacturers may at their option select any of the specified passenger seats and aircraft safety belts for use in the inversion test. A complete listing of all FAA-approved aircraft passenger seats and safety belts can be found in the FAA's Advisory Circular AC 20-36, which is updated annually. By adopting this approach, NHTSA is assuming that the simulated passenger seat shown in Figure 6 and each of the FAA-approved

passenger seats are equivalent for the purposes of the inversion test, and that the slight differences between those seats will not make a difference in whether a restraint passes or fails the inversion test. A similar assumption is made with respect to each of the FAA-approved safety belts. The agency has adopted a similar approach in some other standards. See, e.g., S3 of Standard No. 214, *Side door strength* (49 CFR 571.214). Should the agency assumption of equivalence be shown to be incorrect, NHTSA would amend the standard to specify those seats and safety belts which must be used for the inversion test. However, there is no reason to be that restrictive at this time.

Once the child restraint and test dummy have been secured in place in the representative aircraft passenger seat, the notice proposed that the seat be rotated around a horizontal axis at a rate of 35 to 45 degrees per second to an angle of 180 degrees, and the rotation would be stopped when it reaches an angle of 180 degrees. The commenter stated that this language was indefinite because it did not specify the starting acceleration and stopping deceleration for the rotation. The commenter stated that the test would be more severe if the rotation is begun with a sudden jerk and halted by banging the combination against a stop positioned at 180 degrees than if it were started and stopped more gradually. However, the proposed language does not indicate which of these procedures is to be used for the testing.

NHTSA agrees with the commenter on this point, and the language of this final rule specifies that the inversion test should be conducted to allow not less than $\frac{1}{2}$ second and not more than 1 second for the seat to achieve the required rate of rotation and to be stopped from that rate of rotation. These rates of acceleration and deceleration were the ones used in the NHTSA-FAA joint testing program.

The commenter also stated that there were some minor typographical errors in section S8.2.3, S8.2.4, and S8.2.5, and that the explanatory language beneath Figure 6 needed to be slightly clarified. NHTSA has made each of these requested changes in this final rule.

As discussed above, NHTSA has decided to clarify the test procedures and criteria for determining compliance with the inversion test specified in Standard No. 213. These requirements of this inversion test are optional, and need only be followed by those manufacturers which choose to certify their child restraints for use in aircraft as well as in motor vehicles.

Manufacturers which choose to certify their products only for use in motor vehicles will not be adversely affected by an early effective date for these amendments. The amendments made by this notice do not change the fundamental performance requirement that those manufacturers which choose to also certify their products for use in aircraft will have to meet; the amendment benefits the manufacturers by clarifying the test procedure. Accordingly, I find good cause for making the amendments in this rule effective upon publication in the Federal Register.

The NHTSA has analyzed this rule and determined that it is neither "major" within the meaning of Executive Order 12291 nor "significant" within the meaning of the Department of Transportation regulatory policies and procedures. No additional requirements are imposed for restraints to be certified for use in aircraft, and no additional requirements are imposed for those restraints to be certified only for use in motor vehicles. These amendments simply clarify the testing procedures to be followed for child restraint systems which the manufacturer chooses to certify for use in aircraft. Since the impacts of this rule are minimal, a full regulatory evaluation has not been prepared.

In accordance with the Regulatory Flexibility Act, the NHTSA has evaluated the impacts of this action on small entities. Based upon this evaluation, I certify that these amendments to Standard No. 213 will not have a significant economic impact on a substantial number of small entities. Accordingly, no regulatory flexibility analysis has been prepared. This certification is based on the discussion above pursuant to Executive Order 12291: That is, these amendments only clarify the existing requirements without adding any further requirements. Thus, there should be no impact on child restraint manufacturers nor on any small organizations and small governmental units which purchase child restraints.

Finally, the agency has considered the environmental implications of this rule in accordance with the National Environmental Policy Act and determined that this rule will not significantly affect the human environment.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles, Rubber and rubber products, Tires.

PART 571—[AMENDED]

In consideration of the foregoing, 49 CFR Part 571.213 is amended to read as follows:

1. Paragraph S4 is amended by revising the definition of "representative aircraft passenger seat" to read as follows:

"Representative aircraft passenger seat" means either a Federal Aviation Administration approved production aircraft passenger seat or a simulated aircraft passenger seat conforming to Figure 6.

2. Paragraph S8 is revised to read as follows:

S8. Requirements, test conditions, and procedures for child restraint systems manufactured for use in aircraft.

Each child restraint system manufactured for use in both motor vehicles and aircraft must comply with all of the applicable requirements specified in Section S5 and with the additional requirements specified in S8.1 and S8.2.

S8.1 Installation instructions. Each child restraint system manufactured for use in aircraft shall be accompanied by printed instructions in the English language that provide a step-by-step procedure, including diagrams, for installing the system in aircraft passenger seats, securing the system to the seat, positioning a child in the system when it is installed in aircraft, and adjusting the system to fit the child. In the case of each child restraint which is not intended for use in aircraft at certain adjustment positions, the following statement, with the manufacturer's restrictions inserted, shall be included in the instructions.

DO NOT USE THE—ADJUSTMENT POSITION(S) OF THIS CHILD RESTRAINT IN AIRCRAFT.

S8.2 Inversion test. When tested in accordance with S8.2.1 through S8.2.5 and adjusted in any position which the manufacturer has not, in accordance with S8.1, specifically warned against using in aircraft, each child restraint system manufactured for use in aircraft shall meet the requirements of S8.2.1 through S8.2.6. The manufacturer may, at its option, use any seat which is a representative aircraft passenger seat within the meaning of S4.

S8.2.1 A representative aircraft passenger seat shall be positioned and adjusted so that its horizontal and vertical orientation and its seat back angle are the same as shown in Figure 6.

S8.2.2 The child restraint system shall be attached to the representative aircraft passenger seat using, at the manufacturer's option, any Federal Aviation Administration approved

aircraft safety belt, according to the restraint manufacturer's instructions for attaching the restraint to an aircraft seat. No supplementary anchorage belts or tether straps may be attached; however, Federal Aviation Administration approved safety belt extensions may be used.

S8.2.3 In accordance with S6.1.2.3.1 through S6.1.2.3.3, place in the child restraint any dummy specified in S7 for testing systems for use by children of the heights and weights for which the system is recommended in accordance with S5.5 and S8.1.

S8.2.4 If provided, shoulder and pelvic belts that directly restrain the dummy shall be adjusted in accordance with S6.1.2.4.

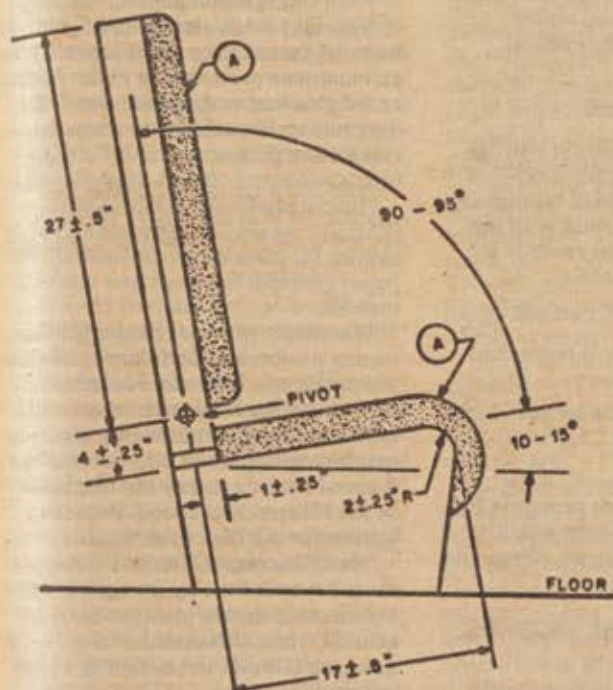
S8.2.5 The combination of representative aircraft passenger seat, child restraint, and test dummy shall be rotated forward around a horizontal axis which is contained in the median transverse vertical plane of the seating surface portion of the aircraft seat and is located one inch below the bottom of the seat frame, at a speed of 35 to 45 degrees per second, to an angle of 180 degrees. The rotation shall be stopped when it reaches that angle and the seat shall be held in this position for three seconds. The child restraint shall not fall out of the aircraft safety belt nor shall the test dummy fall out of the child restraint at any time during the rotation or the three second period. The specified rate of rotation shall be attained in not less than one half second and not more than one second, and the rotating combination shall be brought to a stop in not less than one half second and not more than one second.

S8.2.6 Repeat the procedures set forth in S8.2.1 through S8.2.4. The combination of the representative aircraft passenger seat, child restraint, and test dummy shall be rotated sideways around a horizontal axis which is contained in the median longitudinal vertical plane of the seating surface portion of the aircraft seat and is located one inch below the bottom of the seat frame, at a speed of 35 to 45 degrees per second, to an angle of 180 degrees. The rotation shall be stopped when it reaches that angle and the seat shall be held in this position for three seconds. The child restraint shall not fall out of the aircraft safety belt, nor shall the test dummy fall out of the child restraint at any time during the rotation or the three second period. The specified rate of rotation shall be attained in not less than one half second and not more than one second, and the rotating

combination shall be brought to a stop in not less than one half second and not more than one second.

3. A new Figure 6 would be added at the end of § 571.213, appearing as follows:

12A



"A" represents a 2- to 3-inch thick polyurethane foam pad, 1.5-2.0 pounds per cubic foot density, over 0.020-inch-thick aluminum pan, and covered by 12- to 14-ounce marine canvas. The sheet aluminum pan is 20 inches wide and supported on each side by a rigid structure. The seat back is a rectangular frame covered with the aluminum sheet and weighing between 14 and 15 pounds, with a center of mass 13 to 16 inches above the seat pivot axis. The mass moment of inertia of the seat back about the seat pivot axis is between 195 and 220 ounce-inch-second². The seat back is free to fold forward about the pivot, but a stop prevents rearward motion. The passenger safety belt anchor points are spaced 21 to 22 inches apart and are located in line with the seat pivot axis.

FIGURE 6: SIMULATED AIRCRAFT PASSENGER SEAT

Secs. 103, 119, Pub. L. 89-563, 80 Stat. 718 (15 U.S.C. 1392 and 1407); delegation of authority (49 CFR 1.50)

Issued on April 10, 1985.

Diane K. Steed,

Administrator.

(FR Doc. 85-9211 Filed 4-16-85; 8:45 am)

SELLING CODE 4910-59-M

Proposed Rules

Federal Register

Vol. 50, No. 74

Wednesday, April 17, 1985

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 293

Personnel Records

AGENCY: Office of Personnel Management.

ACTION: Proposed rulemaking.

SUMMARY: Under the authority of 5 U.S.C. 2951(2) and Executive Orders 12107 and 12196, the Office of Personnel Management (Office) proposes to establish an Employee Medical File System to manage Federal civilian employee medical records. Therefore, the Office is proposing new regulations to provide more effective management of Federal civilian employee medical records. These regulations are necessary to bring about effective records management of these highly sensitive records. Elsewhere in this issue is a related Privacy Act System Notice pertaining to these records.

DATE: Written comments will be considered if received June 17, 1985.

ADDRESS: Send or deliver written comments to the Assistant Director for Workforce Information, Office of Personnel Management, Room 5415, 1900 E Street NW., Washington, D.C. 20415.

FOR FURTHER INFORMATION CONTACT: William H. Lynch, (202) 632-5433.

SUPPLEMENTARY INFORMATION: The proposed regulations provide uniform policies and procedures for maintaining and disposing of medical records for Federal civilian employees. Management of Federal civilian employee medical records will be accomplished through procedures governing a newly established Employee Medical File System (EMFS) which, in accordance with the Privacy Act, identifies records included in the system, describes retention and storage requirements, and describes necessary access and disclosure procedures.

E.O. 12291, Federal Regulation

The Office has determined that this is not a major rule as defined under Section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because it is concerned only with the administration of medical records for Federal civilian employees.

List of Subjects in 5 CFR Part 293

Archives and records, Government employees, Privacy.

U.S. Office of Personnel Management.
Donald J. Devine,
Director.

Accordingly, the Office proposes to add a new Subpart E to Part 293, Title 5, Code of Federal Regulations, to read as follows:

PART 293—PERSONNEL RECORDS

Subpart E—Employee Medical File System Records

- Sec.
- 293.501 Applicability of regulations.
 - 293.502 Definitions.
 - 293.503 Implementing instructions.
 - 293.504 Composition of, and access to, the Employee Medical File System.
 - 293.505 Establishment of Employee Medical Folder.
 - 293.506 Ownership of the Employee Medical Folder.
 - 293.507 Maintenance and content of the Employee Medical Folder.
 - 293.508 Type of folder to be used.
 - 293.509 Use of existing Employee Medical Folders upon transfer or reemployment.
 - 293.510 Disposition of Employee Medical Folders.
 - 293.511 Retention schedule.

Authority: 5 U.S.C. 2951(2); E.O. 12107 and 12196.

Subpart E—Employee Medical File System Records

§ 293.501 Applicability of regulations.

The applicability of this subpart is identical to that contained in § 293.301.

§ 293.502 Definitions.

For the purpose of this Subpart:

"Agency" means an executive agency as defined in 5 U.S.C. 105.

"Employee" is defined at 5 U.S.C. 2105 and does not include student volunteers or contractors employees.

"Employee Assistance and Counseling Record" means the record created when an employee participates in the agency assistance/counseling program (e.g., drug or alcohol abuse or personal counseling programs under Pub. L. 91-616, 92-255, and 79-858, respectively).

"Employee Medical File System (EMFS)" means the agency's complete system (automated, microformed, and paper records) for employee medical records.

"Employee Medical Folder (EMF)" means a separate file folder established to contain all of the medical records designated for long-term retention, which will be maintained by the employing agency during the employee's Federal service and ultimately be stored in the National Personnel Records Center for the life of the record.

"Epidemiological Record" means a record maintained by an agency or subelement thereof as a result of an official medical research study conducted under the authority of that agency.

"Implementing Instructions" means any form of internal agency issuance that provides the guidance required in § 293.503 and any other implementing instructions the agency deems appropriate.

"Medical Record" means a chronological, cumulative record, regardless of the form or process by which it is maintained (e.g., paper document, microfiche, microfilm, or automatic data processing media), of information about health status developed on an employee and related to employment including personal and occupational health histories and the opinions and written evaluations generated in the course of diagnosis and/or treatment by medical health care professionals and technicians. For the purposes of these regulations the term medical records also means employee on-the-job exposure and injury records.

"Non-personal Record" means any agency aggregate/statistical record or report resulting from studies covering employees or resulting from studies of the work-site environment.

"Patient Record" means a record of treatment created when the person is admitted to or voluntarily seeks treatment at a health care facility for

non job-related reasons that are maintained by that health care facility. Records maintained by an agency dispensary are not patient records for the purposes of these regulations when they result as a condition of employment or relate to an on-the-job occurrence.

§ 293.503 Implementing Instructions.

Agencies must issue internal instructions describing how their EMFS is to be implemented. These instructions must—

- (a) Describe overall operation of the system within the agency including the designation of the agency official (the agency medical officer, if there is one) who will manage these records.
- (b) Be prepared with joint participation by agency medical, health and safety, and personnel officers;
- (c) Describe where and under whose custody employee medical records will be physically maintained;
- (d) Designate which agency office(s) will be responsible for deciding when and what medical records are to be disclosed either to other agency officials or outside the agency;
- (e) Ensure proper records retention and security, preserve confidentiality of doctor/patient relationships, and provide that personnel management decisions based on the records are appropriate and justified;
- (f) Be consistent with Office regulations relating to personnel actions when medical evidence is a factor (5 CFR Parts 339, 432, 630, 752, and 831);
- (g) Provide guidance on how an accounting of any record disclosure, as required by the Privacy Act (5 U.S.C. 552a(c)), will be done in a way that ensures that the accounting will be available for the life of the EMF;
- (h) Provide for the creation of an EMF for all employees transferring to another agency or who leave government service and describe when the EMF is to be created on an employee transferring within the same agency;
- (i) Ensure a right of access (consistent with any special Privacy Act handling procedures invoked) to the records, in whatever format they are maintained, by the employee or a designated representative;
- (j) Ensure that a knowledgeable official determines that all appropriate long-term medical records are in an EMF prior to its transfer to another agency, the National Personnel Records Center (NPRC), or to another office within the same employing agency;
- (k) Ensure that all long-term medical records an agency receives in an EMF are maintained, whether in that same EMF or by some other agency procedure, and forwarded to a

subsequent employing agency or to NPRC;

(l) Ensure that, if medical records are to be physically located in the same office as the Official Personnel Folder (OPF), the records are maintained physically apart from each other;

(m) Sets forth a different policy, particularly regarding the disclosure of records, for records in the nature of physician treatment records (generally not appropriate for disclosure to non-medical officials) as distinguished from other medical reports properly available to officials making management decisions concerning the employee;

(n) Provide guidance that distinguishes records properly subject to this part from those subject to different rules (e.g., Postal Service or Foreign Service employee medical records), particularly in Privacy Act and Freedom of Information Act matters;

(o) Ensure that guidance regarding the processing of Privacy Act matters is consistent with Office regulations at 5 CFR Parts 293 and 297 implementing this statute; and

(p) Ensure that no security classification is assigned to an EMF by including therein a medical record that has such a classification. In this regard, the agency creating the classified medical record is required to retain it separately from the EMF while placing a notice in the EMF of its existence and describing where requests for this record are to be submitted.

§ 293.504 Composition of, and access to, the Employee Medical File System.

(a) All employee medical records (except employee assistance/counseling, patient, non-personal, and epidemiological records) whether they are maintained in an automated, microform, or paper mode, and wherever located in the agency, are part of the EMFS. The records maintained in the EMFS are part of a Government-wide Privacy Act system of records established by the Office. Agencies have the responsibility to ensure that such documents are maintained in accordance with the Office's Privacy Act regulations in Part 297 of this chapter, with the agency's instructions implementing those regulations, and with the retention schedule for employee medical records stipulated in § 293.511.

Note.—While patient records pertaining to an employee are not required to be included as a medical record within the EMFS, under certain conditions, copies of such records may be included in the system.

(b) Agencies must provide employees access to their own medical records consistent with Office regulations

contained in § 297.204(c) of this chapter. When access can be provided directly to the employee, it must also be provided to the employee's representative designated in writing. Disclosure of an employee's medical records to agency officials (both medical and non-medical) will be granted only when the specific information sought is needed for the performance of official duties and consistent with agency implementing instructions, particularly § 293.503(m).

(c) Other requests for employee medical files made to the custodian of the records must be processed in accordance with the disclosure provisions of the Privacy Act (5 U.S.C. 552a(b)) and the Office's regulations at 5 CFR 297.

(d) Processing of a Privacy Act request for amendment of medical records must be consistent with the Office's regulations contained in Part 297 of this chapter regarding amendment of records.

§ 293.505 Establishment of Employee Medical Folder.

(a) As provided by the Office's instructions and in FPM Supplement 293-31, agencies must establish an EMF when the employee leaves the employing agency; agencies may also establish an EMF for active employees if the agency chooses. An agency must request the transfer of an existing EMF at the same time it requests the transfer of an employee's OPF only when the conditions described in § 293.510 exist, using the procedures contained in § 293.306.

(b) Neither the original medical documents nor duplicates are to be retained in the OPF. Prior to the establishment of an EMF for a separating employee, as such records are created, they must be maintained physically apart from the OPF, although they may be kept in the same office.

(c) Records in an EMF, whether or not located in an office other than where the OPF is maintained, must be properly safeguarded using procedures ensuring equal or greater levels of protection as those in § 293.106 of this part. Disclosures must be made only to those authorized to receive them, as described in § 293.504(b), and employees must be able to ascertain from agency implementing instructions the location of all of their medical records. An EMF must be under the control of a specifically designated medical, health, safety, or personnel officer as prescribed in the agency's implementing internal issuance.

§ 293.506 Ownership of the Employee Medical Folder.

The EMF of each employee in a position subject to civil service rules and regulations is part of the records of the Office. When the EMF also contains medical records created during employment in a position not subject to the civil service (e.g., with the Postal Service), the EMF is then part of the records of both the Office and the former employer.

§ 293.507 Maintenance and content of the Employee Medical Folder.

The agency head must maintain all appropriate employee medical records in the EMFS, as specified in the Office's instructions and in FPM Supplement 293-31. When an EMF is established for an employee, as required in § 293.504, the agency's EMFS must be searched to obtain all records designated for retention in the EMF.

§ 293.508 Type of folder to be used.

Each agency must use a folder that (1) has been specifically provided, pursuant to a request by the Office, by Federal Supply Service contracts; (2) has been authorized by the Office for use by a specific agency; or (3) in the case of an EMF containing records under joint control of the Office and another agency, has been jointly authorized.

§ 293.509 Use of existing Employee Medical Folders upon transfer or reemployment.

The requirements of § 293.306, regarding the use of existing OPFs, apply to the use of existing EMFs upon the employee's transfer to or reemployment in a new employing agency (consistent with § 293.510).

§ 293.510 Disposition of Employee Medical Folders.

(a) When an employee transfers to another Federal agency, the EMF must be transferred to the gaining agency at the same time as the employee's OPF. The EMF is only to be transferred directly to the gaining agency's designated manager (medical, health, safety, or personnel officer) of the EMFS.

(b) In accordance with the instructions in § 293.307, when an employee is separated from the Federal service, the EMF must be forwarded to NPRC with the OPF.

(c) When a former Federal employee is re-employed by an agency, and that agency believes that an EMF exists, either at the last employing agency or at the NPRC, the agency will request the EMF, but no sooner than 30 days after the date of the new appointment. No EMF will be routinely retrieved during

the initial review process (as is done with the OPF) except where authority exists for the agency to require a medical evaluation prior to reaching a decision on employability. EMFs are to be transferred by the NPRC only to the agency designated manager (medical, health, safety, or personnel officer) of that agency's EMFs.

§ 293.511 Retention schedule.

(a) Temporary medical records, as defined in FPM Supplement 293-31, must not be placed in a newly-created EMF for a separating employee and must be removed from an already existing EMF, before transfer to another agency or to the NPRC. Such records must be disposed of in accordance with General Records Schedule (GRS) 1, item 21, issued by National Archives and Records Administration (NARA).

(b) Medical records considered to be long-term records, as defined in FPM Supplement 293-31, must be maintained for the duration of employment, plus 30 years. Therefore, upon separation the records must be provided to the employee's new agency or they must be transferred to the NPRC, which will dispose of them in accordance with General Records Schedule (GRS) 1, item 21, issued by NARA.

[FR Doc. 85-9284 Filed 4-16-85; 8:45 am]
BILLING CODE 6325-01-M

DEPARTMENT OF AGRICULTURE**Agricultural Marketing Service****7 CFR Part 52****United States Standards for Grades of Canned Clingstone Peaches**

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: The purpose of this proposed rule is to revise the voluntary U.S. Standards for Grades of Canned Clingstone Peaches. The proposed rule was developed by the United States Department of Agriculture (USDA) at the request of major segments of the canned clingstone peach industry. Its effect would be to better serve the needs of the canned clingstone peach industry and allow for more orderly marketing of canned clingstone peaches.

DATE: Comments must be received on or before May 17, 1985.

ADDRESS: Interested persons are invited to submit written comments concerning this proposal. Comments must be sent in duplicate to the Docket Clerk, Fruit and Vegetable Division, Agricultural

Marketing Service, U.S. Department of Agriculture, Room 2069, South Building, Washington, D.C. 20250. Comments should reference the date and page number of this issue of the Federal Register and will be made available for public inspection in the office of the Docket Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT:

Paul Jennings, Processed Products Branch, Fruit and Vegetable Division, Agricultural Marketing Service, U.S. Department of Agriculture, Washington, D.C. 20250, Telephone (202) 447-6247.

SUPPLEMENTARY INFORMATION: This rule has been reviewed under USDA procedures and Executive Order 12291 and has been designated as a "nonmajor" rule. It will not result in an annual effect on the economy of \$100 million or more. There will be no major increase in cost or prices for consumers, individual industries, Federal, State, or local government agencies; or geographic regions. It will not result in significant effects on competition, employment, investments, productivity, innovations, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

William T. Manley, Deputy Administrator, Agricultural Marketing Service, has certified that this action will not have a significant economic impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act, Pub. L. 96-354 (5 U.S.C. 601), because it reflects current marketing practices.

Based on industry recommendations, the voluntary grade standards for canned clingstone peaches were revised to institute an "attributes standards" type of grading on July 1, 1978. Before that time, the grade standards utilized the "variables standards" type of grading. Even though the attributes standards may have greater statistical validity, the clingstone peach processing industry claims that they are more cumbersome in their practical application than the former variables standards. Therefore, major segments of the canned clingstone peach industry now believe that attributes standards do not best serve their needs. They believe it is difficult to communicate quality levels between processors, buyers, brokers, and other users through these standards.

Under the attributes standards, one type or several types of physical defects may be present in each classification. The classifications are minor, major, severe, and critical. This allows more of

an individual type of defect to be present than under the variables standards in the absence of other types of defects within the classification. For example, defects such as color, blemishes, and mechanical damage are grouped and their sum is used to determine compliance with the classification tolerance. Such determinations of tolerance compliance could be based solely on blemishes if no color defects or mechanical damage is present. The clingstone peach industry has asked for standards, such as the previous variables standards, that require each defect to be separately classified without grouping with other defects. Therefore, in the above example, if the variables standards were used, the number of blemishes allowed to meet the tolerance would be set without regard to whether color defects or mechanical damage were present. In addition to the individual tolerances, the sample would also have to meet a minimum total score. The previous standards used this concept and this proposal would revise the current attributes standards type of grading to variables standards type of grading that would be basically the same as the former standards.

List of Subjects in 7 CFR Part 52

Fruits and vegetables, Food grades, Standards.

PART 52—[AMENDED]

Accordingly, the United States Standards for Grades of Canned Clingstone Peaches (7 CFR 52.2561–52.2576) are proposed to be amended as follows:

1. The Table of Contents of the Subpart is amended by revising the following section headings to read as follows:

52.2562	Styles.
52.2563	Grades.
52.2564	Grades of canned "solid pack" clingstone peaches.
52.2570	Ascertaining the grade.
52.2571	Ascertaining the rating for the factors which are scored.
52.2572	Color.
52.2573	Uniformity of size and symmetry.
52.2574	Absence of defects.
52.2575	Character.
52.2576	Ascertaining the grade of a lot.

2. In Part 52, §§ 52.2562, 52.2563 and 52.2564 are revised to read as follows:

§ 52.2562 Styles.

(a) "Halves" or "Halved" canned peaches are peeled and pitted peaches,

cut approximately in half along the suture from stem to apex.

(b) "Quarters" or "Quartered" canned peaches are halved peaches cut into two approximately equal parts.

(c) "Slices" or "Sliced" canned peaches are peeled and pitted peaches cut into sectors smaller than quarters.

(d) "Dice" or "Diced" canned peaches are peeled and pitted peaches cut into approximate cubes.

(e) "Whole" canned peaches are peeled, unpitted, whole peaches with or without stems removed.

(f) "Mixed pieces of irregular sizes and shapes" are peeled, pitted, and cut units of canned peaches that are predominantly irregular in size and shape which do not conform to a single style of halves, quarters, slices, or dice and which may consist of:

(1) Units (commonly called "salad cuts" or "salad pieces") which may have been prepared originally as peach halves but which are irregular in size and shape in that more than one-fourth of the unit appears to have been removed at the outer curved surface and which have been cut further into pieces;

(2) Units which may have been prepared originally as peach slices but which are irregular in size and shape in that they have been cut further into pieces; or

(3) Mixtures of two or more of the following styles which may or may not be of normal shape: Halves, quarters, slices, or diced.

§ 52.2563 Grades.

(a) "U.S. Grade A" is the quality of halves, quarters, slices, dice, or whole canned clingstone peaches that possess similar varietal characteristics, that possess a normal flavor and odor, that possess a good color, that are practically uniform in size and symmetry for the applicable style, that are practically free from defects, that possess a good character, and that for those factors which are scored in accordance with the scoring system outlined in this subpart the total score is not less than 90 points: Provided, that halves, quarters, slices, dice, or whole canned clingstone peaches may possess a reasonably good color, may be reasonably uniform in size and symmetry, and may possess a reasonably good character, if the total score is not less than 90 points.

(b) "U.S. Grade B" is the quality of halves, quarters, slices, dice, whole, or mixed pieces of irregular sizes and shapes of canned clingstone peaches that possess similar varietal characteristics; that possess a normal flavor and odor, that possess a reasonably good color; that are reasonably uniform in size and

symmetry for the applicable style, that are reasonably free from defects, that possess a reasonably good character, and that for those factors which are scored in accordance with the scoring system outlined in this subpart the total score is not less than 80 points. Provided, that halves, quarters, slices, dice, or whole canned clingstone peaches may be fairly uniform in size and symmetry if the total score is not less than 80 points.

(c) "U.S. Grade C" is the quality of halves, quarters, slices, diced, whole, or mixed pieces of irregular sizes and shapes of canned clingstone peaches that possess similar varietal characteristics; that possess a normal flavor and odor, that possess a fairly good color, that are fairly uniform in size and symmetry for the applicable style, that are fairly free from defects, that possess a fairly good character, and that for those factors which are scored in accordance with the scoring system outlined in this subpart the total score is not less than 70 points.

(d) "U.S. Grade D" is the quality of halves, quarters, slices, diced, whole, or mixed pieces of irregular sizes and shapes of canned clingstone peaches that may possess dissimilar varietal characteristics; that possess a normal flavor and odor, that possess a fairly good color, that may vary in size and symmetry for the applicable style; that are fairly free from defects except for crushed and broken units in the styles of halves, quarters, or whole style; that possess a noticeable variability in character, and that for those factors which are scored in accordance with the scoring system outlined in this subpart the total score is not less than 60 points. Canned clingstone peaches of this grade may or may not meet the minimum standards of quality for canned peaches issued pursuant to the Federal Food, Drug, and Cosmetic Act.

(e) "Substandard" is the quality of canned clingstone peaches that fails to meet the applicable requirements of U.S. Grade C or of U.S. Grade D and is the quality of canned clingstone peaches that may or may not meet the minimum standards of quality for canned peaches issued pursuant to the Federal Food, Drug, and Cosmetic Act.

§ 52.2564 Grades of canned "solid-pack" clingstone peaches.

(a) "U.S. Grade C Solid-Pack" is the quality of halves, quarters, slices, dice, or mixed pieces of irregular sizes and shapes of canned "solid-pack" clingstone peaches that possess a normal flavor and odor; that possess a fairly good color; that are fairly free from defects for canned "solid-pack"

clingstone peaches; that possess a fairly good character for "solid-pack" clingstone peaches; and that for those factors which are scored in accordance with the scoring system outlined in this subpart the total score is not less than 70 points.

(b) "Substandard Solid-Pack" is the quality of halves, quarters, slices, dice, or mixed pieces of irregular sizes and shapes of canned "solid-pack" clingstone peaches that fail to meet the requirements of "U.S. Grade C Solid-Pack."

3. In Part 52, §§ 52.2570 through 52.2575 are revised to read as follows:

§ 52.2570 Ascertaining the grade.

(a) *General.* In addition to considering other requirements outlined in the standards the following quality factors are evaluated:

(1) Factors not rated by score points in canned clingstone peaches other than "solid-pack" clingstone peaches are:

- (i) Varietal characteristics.
- (ii) Flavor and odor.

(2) Factor not rated by score points in "solid-pack" clingstone peaches: Flavor and odor.

(3) Factors rated by score points. The relative importance of each factor which is scored is expressed numerically on the scale of 100. The maximum number of points that may be given such factors are:

	Points
(i) Color	20
(ii) Uniformity of size and symmetry	20
(iii) Absence of defects	30
(iv) Character	30
Total score	100

(b) *Definition of flavor and odor.*—"Normal flavor and odor" means that the canned peaches are free from objectionable flavors and odors of any kind.

§ 52.2571 Ascertaining the rating for the factors which are scored.

The essential variations within each factor which is scored are so described that the value may be ascertained for each factor and expressed numerically. The numerical range within each factor which is scored is inclusive (for example, "18 to 20 points" means "18, 19, or 20 points").

§ 52.2572 Color.

(a) *General.* (1) The color of canned clingstone peaches other than canned "spiced" peaches refers to the predominant and characteristic color on the surface of whole units, and the outside surfaces of other units, except the cut surfaces of such units are also

considered when adversely affected by discoloration. Units other than whole on which the pit cavity is abnormally discolored are considered under the factor of absence of defects only.

(2) The factor of color for canned "spiced" peaches is not based on any detailed requirement and is not scored but the color shall be normal for canned "spiced" peaches; the other three factors (uniformity of size and symmetry, absence of defects, and characters as applicable) are scored and the total is multiplied by 100 and divided by 80, dropping any fractions to determine the total score.

(b) *"A" classification.* Canned clingstone peaches that possess a good color may be given a score of 18 to 20 points. Mixed pieces of irregular sizes and shapes that score 18 to 20 points shall not be graded above U.S. Grade B, regardless of the total score for the product (this is a partial limiting rule). "Good color" means that the peaches possess a bright color ranging from yellowish orange to orange yellow; and that there may be present units which possess "reasonably good color" as follows:

(1) In the style of halves, quarters, slices, or whole, not more than 10 percent by count, of the units may possess "reasonably good color"; or one unit in a container is permitted to possess "reasonably good color"; Provided, that in all containers comprising the sample such units do not exceed an average of 10 percent of the total number of units; and

(2) In the styles of dice or mixed pieces of irregular sizes and shapes, not more than 10 percent, by weight, of the drained peaches may possess "reasonably good color".

(c) *"B" classification.* Canned clingstone peaches that possess a reasonably good color may be given a score of 16 or 17 points. Mixed pieces of irregular sizes and shapes that fall into this classification shall not be graded above U.S. Grade B, regardless of the total score for the product (this is a partial limiting rule). "Reasonably good color" means that the canned clingstone peaches possess a reasonably bright color that may fail to meet minimum color requirements for Grade A but is equal to or better than light orangish-yellow, that the units may possess slight discoloration due to oxidation, pit pigmentation, or other causes which does not more than slightly affect the appearance or eligibility, or both, of the product; and that there may be present units which possess "fairly good color" as follows:

(1) In the style of halves, quarters, slices, or whole, not more than 10

percent, by count, of the units may possess "fairly good color;" or one unit in a container is permitted to possess color: Provided, That in all containers comprising the sample such units do not exceed an average of 10 percent of the total number of units; and

(2) In the style of dice or mixed pieces of irregular sizes and shapes, not more than 10 percent, by weight, of the drained peaches may possess "fairly good color."

(d) *"C", "D", and "C-SP" classification.* Canned clingstone peaches and canned solid-pack clingstone peaches that possess a fairly good color may be given a score of 14 or 15 points. Canned clingstone peaches or canned "solid-pack" clingstone peaches that fall into this classification shall not be graded above U.S. Grade C or U.S. Grade C Solid-Pack, whichever is applicable, regardless of the total score for the product (this is a limiting rule). "Fairly good color" means that the peaches possess a color that may fail to meet minimum color requirements for Grade B, but is equal to or better than greenish-yellow; that the units may possess slight discoloration due to oxidation, pit pigmentation or other causes which do not materially affect the appearance or edibility, or both, of the product; and that the units may possess other color as follows:

(1) In the style of halves, quarters, slices, or whole, not more than 10 percent, by count, of the units may fail to meet the minimum color for Grade C or may be off-color; or one unit in a container is permitted to possess such color: Provided, That in all containers comprising the sample such units do not exceed an average of 10 percent of the total number of units.

(2) In the style of dice or mixed pieces of irregular sizes and shapes, not more than 10 percent, by weight, of the drained peaches may consist of units that fail to meet the minimum color for Grade C or may be off-color: Provided, That such units do not materially affect the appearance of the product.

(e) *"SSId" and "SSId-SP" classification.* Canned clingstone peaches and canned "solid-pack" clingstone peaches that fail to meet the requirements of paragraph (d) of this section may be given a score of 0 to 13 points and shall not be graded above Substandard or Substandard Solid-Pack, whichever is applicable, regardless of the total score for the product (this is a limiting rule).

§ 52.2573 Uniformity of size and symmetry.

(a) *General.* The factor of uniformity of size and symmetry for mixed pieces of irregular sizes and shapes of canned clingstone peaches and all applicable styles of canned "solid-pack" clingstone peaches is not based on any detailed requirements and is not scored; the other three factors (color, absence of defects, and character, as applicable) are scored and the total is multiplied by 100 and divided by 80, dropping any fractions to determine the total score.

(b) *Off-suture cuts.* "Off-suture cut" in halved or quartered canned clingstone peaches means a halved or quartered unit which has been cut at a distance from the suture greater than three-eighths inch at the widest measurement from the suture.

(c) *Partially detached or detached piece.* A "partially detached or detached piece" in halved canned clingstone peaches means a unit which has the appearance of a slice resulting from an off-suture cut or from improper cutting and which may or may not be attached to the half from which cut. In determining the applicable allowances in terms of percentage by count, a partially detached piece together with the half to which it is partially attached is considered as one unit or a detached piece with the half from which detached or together with any other half is considered as one unit.

(d) *Partial slice.* A "partial slice" in the style of slices is a unit that has had the semblance of a slice with respect to thickness and shape but is less than three-fourths of an apparent full slice and that does not bear marks of crushing. In determining the allowances in terms of percentage by count, partial slices aggregating the equivalent of an average size slice shall be considered as one unit.

(e) *Sliver.* A "sliver" in the style of slices is a sector that is substantially smaller than the general size of slices or that weighs 3 grams or less.

(f) *Slab.* A "slab" in the style of slices is a portion of a unit which does not conform to the shape of a definite slice due to improper cutting.

(g) *"A" Classification.* Halves, quarters, slices, dice, or whole canned clingstone peaches that are practically uniform in size and symmetry may be given a score of 18 to 20 points. "Practically uniform in size and symmetry" has the following meanings with respect to the following styles of canned clingstone peaches:

(1) *Halves, quarters, and whole.* The units are very symmetrical and the weight of the largest full-size unit does not exceed the weight of the smallest

full-size unit by more than 40 percent; the weight of each half is not less than three-fifths oz; the weight of each quarter is not less than three-tenths tenths oz; and not more than 10 percent, by count, of the units in the style of halves or quarters may possess off-suture cuts or partially detached or detached pieces, or any combination thereof. One unit in a container is permitted to possess an off-suture cut or partially detached or detached piece if such unit exceeds the allowance of 10 percent, by count: Provided, that in all containers comprising the sample such units do not exceed an average of 10 percent of the total number of units.

(2) *Slices.* Not more than a total of 5 percent, by count, of the units may be partial slices, slivers, and slabs: Provided, that not more than 2½ percent, by count, are slabs; and excluding partial slices, slivers, and slabs that may be present, the variation in size and symmetry of the other units does not affect more than slightly the appearance of the product.

(3) *Dice.* Not more than 10 percent, by weight, of the drained clingstone peaches may be units that are more than three-fourths inch in their greatest edge dimension or are of such size as to pass through a five-sixteenth inch square opening.

(h) *"B" Classification.* Halves, quarters, slices, dice, or whole canned clingstone peaches that are reasonably uniform in size and symmetry may be given a score of 16 or 17 points. "Reasonably uniform in size and symmetry" has the following meanings with respect to the follows styles of canned clingstone peaches.

(1) *Halves, quarters, and whole.* The units are reasonably symmetrical and the weight of the largest full-size unit does not exceed the weight of the smallest full-size unit by more than 60 percent; the weight of each half is not less than three-fifths oz; the weight of each quarter is not less than three-tenths oz; and not more than 20 percent, by count, of the units in the style of halves or quarters may possess off-suture cuts or partially detached or detached pieces, or any combination thereof. One unit in a container is permitted to possess an off-suture cut or partially detached or detached piece if such unit exceeds the allowance of 20 percent, by count: Provided, that in all containers comprising the sample such units do not exceed an average of 20 percent of the total number of units.

(2) *Slices.* Not more than a total of 10 percent, by count, of the units may be partial slices, slivers, and slabs: provided, that not more than 5 percent, by count, are slabs; and excluding

partial slices, slivers, and slabs that may be present, the variation in size and symmetry of the other units does not more than materially affect the appearance of the product.

(3) *Dice.* Not more than 15 percent, by weight of the drained clingstone peaches may be units that are more than three-fourths inch in their greatest edge dimension or are of such size as to pass through a five sixteenth inch square opening.

(i) *"C" Classification.* Halves, quarters, slices, dice, or whole canned clingstone peaches that are fairly uniform in size and symmetry may be given a score of 14 or 15 points. Canned clingstone peaches that fall into this classification shall not be graded above U.S. Grade B, regardless of the total score for the product (this is a partial limiting rule). "Fairly uniform in size and symmetry" has the following meanings with respect to the following styles of canned clingstone peaches:

(1) *Halves, quarters, and whole.* The units may vary in size, thickness, and symmetry and the weight of the largest full-size unit may be not more than twice the weight of the smallest full-size unit; the weight of each half is not less than three-fifths oz; the weight of each quarter is not less than three-tenths oz; and not more than 40 percent, by count, of the units in the style of halves or quarters may possess off-suture cuts or partially detached or detached pieces, or any combination thereof: Provided, that the presence of such units does not give the appearance of canned peaches of "Mixed Pieces of Irregular Sizes and Shapes" or canned peaches that are "Unevenly Trimmed."

(2) *Slices.* Not more than a total of 20 percent, by count of the units may be partial slices, slivers, and slabs: Provided, that not more than 10 percent, by count, are slabs; and excluding partial slices, slivers, and slabs that may be present, the balance of slices may vary noticeably in size, thickness and symmetry.

(3) *Dice.* Not more than 20 percent, by weight of the drained clingstone peaches may be units that are more than three-quarters inch in their greatest edge dimension or are of such size as to pass through a five-sixteenth inch square opening.

(j) *"D" and "SSd" Classification.* Canned clingstone peaches of the applicable styles which fail to meet paragraph (i) of this section may be given a score of 0 to 13 points and shall not be graded above the following stated grade, regardless of the total score for the product (this is a limiting rule):

(1) Halves, quarters, or whole canned clingstone peaches in which the weight of the largest full-size unit is more than twice the weight of the smallest full-size unit shall not be graded above U.S. Grade D and are also "Below Standard in Quality—Mixed Sizes."

(2) Halves of canned clingstone peaches in which the weight of any half is less than three-fifths oz shall not be graded above U.S. Grade D and are also "Below Standard in Quality—Small Halves."

(3) Quarters of canned clingstone peaches in which the weight of any quarter is less than three-tenths oz shall not be graded above U.S. Grade D and are also "Below Standard in Quality—Small Quarters."

(4) Slices and dice canned clingstone peaches shall not be graded above U.S. Grade D.

§ 52.2574 Absence of defects.

(a) *General.* The factor of absence of defects refers to the degree of freedom from harmless extraneous material (such as stems or leaves and portions thereof), from pit material, from units that are crushed or broken for the applicable style, and from any other defects which detract from the appearance or edibility of the product.

(1) *Blemished.* "Blemished" or "blemished units" means units that are blemished with scab, hail injury, discoloration, or other abnormality which affects materially the appearance or edibility, or both, of the unit.

(2) *Crushed or broken.* "Crushed or broken" means that:

(i) A unit in halves, quarters, or whole style of canned clingstone peaches is "crushed" if the unit has definitely lost its normal shape and bears marks of crushing or is otherwise crushed not due to ripeness; and

(ii) A unit in halves, quarters, or whole style of canned clingstone peaches is "broken" if severed into definite parts; halves of canned clingstone peaches that are slightly or partially split from the edge to the pit cavity are not considered broken. Portions equivalent to a full-size unit that has been broken are considered as one unit in determining the percentage by count.

(3) *Pit material.* "Pit material" means any whole pit in all styles other than whole style or any portion of a peach pit, regardless of size, except when whole peach pits or peach kernels are permitted as seasoning ingredients in other than whole style.

(b) *"A" classification.* Halves, quarters, slices, dice, whole, or mixed pieces of irregular sizes and shapes of canned clingstone peaches that are

practically free from defects may be given a score of 27 to 30 points. Mixed pieces of irregular sizes and shapes of canned clingstone peaches that score 27 to 30 points shall not be graded above U.S. Grade B regardless of the total score for the product (this is a partial limiting rule). "Practically free from defects" means that the canned clingstone peaches are practically free from pit material, from harmless extraneous material, and from any defects not specifically mentioned that affect the appearance or edibility of the product, and in addition, has the following meanings with respect to the following styles of canned clingstone peaches:

(1) *Halves, quarters, and whole.* Not more than an average one-eighth square inch of peel for each pound of total contents may be present; not more than 5 percent, by count, of the units may be crushed, or broken; and not more than 5 percent, by count, of the units may be blemished. One unit in a container is permitted to be crushed or broken and one unit in a container is permitted to be blemished if any of such units exceeds the respective allowances of 5 percent by count: Provided, That in all containers comprising the sample such crushed or broken units do not exceed an average of 5 percent of the total number of units and such blemished units do not exceed an average of 5 percent of the total number of units.

(2) *Sliced.* Not more than an average of one-eighth square inch of peel for each pound of total contents may be present: And more than 3 percent, by count, of the units may be blemished. One unit in a container is permitted to be blemished if such unit exceeds the allowance of 3 percent by count: Provided, That in all containers comprising the sample such blemished units do not exceed an average of 3 percent of the total number of units.

(3) *Dice.* Not more than an average of one-eighth square inch of peel for each pound of total contents may be present; and not more than 3 percent, by weight, of drained clingstone peaches may consist of units that are blemished.

(4) *Mixed pieces or irregular sizes and shapes.* Not more than an average of one-eighth square inch of peel for each pound of total contents may be present; and not more than 1 blemished unit for each 32 oz of total contents may be present.

(c) *"B" classification.* Halves, quarters, slices, dice, whole, or mixed pieces of irregular sizes and shapes of canned clingstone peaches that are reasonably free from defects may be given a score of 24 to 26 points. Canned clingstone peaches that fall into this

classification shall not be graded above U.S. Grade B regardless of the total score for the product (this is a limiting rule). "Reasonably free from defects" means that the canned clingstone peaches are practically free from pit material, are reasonably free from harmless extraneous material and from any defects not specifically mentioned that affect the appearance or edibility of the product, and in addition, has the following meanings with respect to the following styles of canned clingstone peaches:

(1) *Halves, quarters, and whole.* Not more than an average of one-half square inch of peel for each pound of total contents may be present; not more than 5 percent, by count, of the units may be crushed, or broken; and not more than 10 percent, by count, of the units may be blemished. One unit in a container is permitted to be crushed or broken and one unit in a container is permitted to be blemished if any of such units exceed the respective allowances of 5 percent and 10 percent, by count: Provided, That in all containers comprising the sample such crushed or broken units do not exceed an average of 5 percent of the total number of units and such blemished units do not exceed an average of 10 percent of the total number of units.

(2) *Sliced.* Not more than an average of one-half square inch of peel for each pound of total contents may be present; and not more than 6 percent, by count, of the units may be blemished. One unit in a single container is permitted to be blemished if such unit exceeds the allowance of 6 percent, by count: Provided, That in all containers comprising the sample such blemished units do not exceed an average of 6 percent of the total number of units.

(3) *Dice.* Not more than an average of one-half square inch of peel for each pound of total contents may be present; and not more than 6 percent, by weight, of drained clingstone peaches may consist of units that are blemished.

(4) *Mixed pieces of irregular sizes and shapes.* Not more than an average of one-half square inch of peel for each pound of total contents may be present; and not more than 1 blemished unit for each pound of total contents may be present.

(d) *"C" classification.* Halves, quarters, slices, dice, whole, or mixed pieces of irregular sizes and shapes of canned clingstone peaches that are fairly free from defects may be given a score of 21 to 23 points. Canned clingstone peaches that fall into this classification shall not be graded above U.S. Grade C regardless of the total

score for the product (this is a limiting rule). "Fairly free from defects" means that the canned clingstone peaches are practically free from pit material, are fairly free from harmless extraneous material and from any defects not specifically mentioned that affect the appearance or edibility of the product, and in addition, has the following meanings with respect to the following styles of canned clingstone peaches:

(1) *Halves, quarters, and whole.* Not more than an average of one square inch of peel for each pound of total contents may be present; not more than 5 percent, by count, of the units may be crushed or broken; and not more than 20 percent, by count, of the units may be blemished. One unit in a container is permitted to be crushed or broken and one unit in a container is permitted to be blemished if any of such units exceed the respective allowances of 5 percent and 20 percent, by count. Provided, That in all containers comprising the sample such crushed or broken units do not exceed an average of 5 percent of the total number of units and such blemished units do not exceed an average of 20 percent of the total number of units.

(2) *Slices, dice, and mixed pieces of irregular sizes and shapes.* Not more than an average of one square inch of peel for each pound of total contents may be present; and not more than 20 percent, by count, of the units may be blemished.

(e) *"D" classification.* Canned clingstone peaches of any style which fail to meet the requirements of paragraph (d) of this section but which meet the requirements of this paragraph may be given a score of 0 to 20 points and shall not be graded above U.S. Grade D, regardless of the total score for the product (this is a limiting rule).

Halves, quarters, or whole canned clingstone peaches that are hereby U.S. Grade D may also be "Below Standard in Quality—Blemished" or "Partly Crushed or Broken" or "Unevenly Trimmed", or combinations thereof.

Canned clingstone peaches of U.S. Grade D with respect to "absence of defects" are practically free from pit material, are fairly free from harmless extraneous material and from any defects not specifically mentioned that affect materially the appearance or edibility of the product, and in addition:

(1) Not more than an average of one square inch of peel for each pound of total contents may be present;

(2) In the style of halves, quarters, or whole, any amount of crushed or broken units may be present; and

(3) Not more than 20 percent, by count, of the units may be blemished. One unit in a container is permitted to

be blemished if such unit exceeds the allowance of 20 percent, by count: Provided, That in all containers comprising the sample such blemished units do not exceed an average of 20 percent of the total number of units.

(f) *"SStd" classification.* Canned clingstone peaches that fail to meet the applicable requirements of paragraph (e) of this section may be given a score of 0 to 20 points and shall not be graded above the following stated grades, as applicable, regardless of the total score for the product (this is a limiting rule).

(1) Halves, quarters, or whole canned clingstone peaches shall not be graded above Substandard and may also be "Below Standard in Quality" for the applicable reasons:

- (i) Not well peeled;
- (ii) Partly crushed or broken;
- (iii) Unevenly trimmed;
- (iv) Blemished.

(2) Slices, dice, or mixed pieces of irregular sizes and shapes of canned clingstone peaches shall not be graded above Substandard and may also be "Below Standard in Quality" for the applicable reasons:

- (i) Not well peeled;
- (ii) Blemished.

(g) *"C-SP" classification.* Halves, quarters, slices, dice, or mixed pieces of irregular sizes and shapes of canned "solid-pack" clingstone peaches that are fairly free from defects for canned "solid-pack" clingstone peaches may be given a score of 21 to 23 points. Canned "solid-pack" clingstone peaches that fall into this classification shall not be graded above U.S. Grade C Solid-Pack, regardless of the total score for the product (this is a limiting rule). "Fairly free from defects for canned 'solid-pack' clingstone peaches" means that the canned "solid-pack" clingstone peaches are practically free from pit material, are fairly free from harmless extraneous material and from any defects not specifically mentioned that affect the appearance or edibility of the product, and in addition, there may be present:

(1) Not more than an average of one square inch of peel for each pound of total contents; and

(2) Not more than 2 blemished units for each pound of total contents.

(h) *"SStd-SP" classification.* Halves, quarters, slices, dice, or mixed pieces of irregular sizes and shapes of canned "solid-pack" clingstone peaches that fail to meet the requirements of paragraph (g) of this section may be given a score of 0 to 20 points and shall not be graded above Substandard Solid-Pack, regardless of the total score for the product (this is a limiting rule).

§ 52.2575 Character.

(a) *General.* The factor of character refers to the degree of ripeness, the texture, and tenderness of the product.

(b) *"A" classification.* Halves, quarters, slices, dice, whole, or mixed pieces of irregular sizes and shapes of canned clingstone peaches that possess a good character may be given a score of 27 to 30 points. Mixed pieces of irregular sizes and shapes of canned clingstone peaches that score 27 to 30 points shall not be graded above U.S. Grade B regardless of the total score for the product (this is a partial limiting rule). "Good character" has the following meanings with respect to the various styles of canned clingstone peaches:

(1) Halves, quarters, slices, and mixed pieces of irregular sizes and shapes. The units are pliable and possess a tender, fleshy texture typical of nature, well-ripened, properly prepared, and properly processed canned clingstone peaches; and units are intact and possess reasonably well-defined edges; and not more than 10 percent, by count, of the units may possess a "reasonably good character". One unit in a container is permitted to possess a "reasonably good character" if such unit exceeds the allowance of 10 percent, by count: Provided, That the appearance or eating quality, or both, is not more than slightly affected by the character of such unit.

(2) *Dice.* The product generally possesses a texture typical of mature, well-ripened, properly prepared, and properly processed canned clingstone peaches; not more than 3 percent, by weight, of the drained clingstone peaches may be excessively frayed or mushy; and the product is otherwise reasonably free from crushed units.

(3) *Whole.* The units possess a tender texture typical of mature, well-ripened, properly prepared, and properly processed canned clingstone peaches; the units are uniformly intact and firm; and not more than 10 percent, by count, of the units may possess a "reasonably good character". One unit in a container is permitted to possess a "reasonably good character" if such unit exceeds the allowance of 10 percent, by count: Provided, That the appearance or eating quality, or both, is not more than slightly affected by the character of such unit.

(c) *"B" classification.* Halves, quarters, slices, dice, whole, or mixed pieces of irregular sizes and shapes of canned clingstone peaches that possess a reasonably good character may be given a score of 24 to 26 points. Mixed pieces of irregular sizes and shapes of canned clingstone peaches that fall into this classification shall not be graded

above U.S. Grade B, regardless of the total score for the product (this is a partial limiting rule). "Reasonably good character" has the following styles of canned clingstone peaches:

(1) *Halves, quarters, slices, and mixed pieces of irregular sizes and shapes.* The units possess a texture typical of mature, properly ripened, properly prepared, and properly processed canned clingstone peaches; the texture is reasonably fleshy, and the units are reasonably tender or the tenderness may be variable within the unit; the units are reasonably intact with not more than slightly frayed edges and may be slightly firm or slightly soft but are not mushy; and not more than 10 percent, but count, of the unit may possess a fairly good character. One unit in a container is permitted to possess such fairly good character if such unit exceeds the allowance of 10 percent, by count: Provided, That the appearance of such unit.

(2) *Dice.* The product generally possess a texture typical of mature, properly ripened, properly prepared, and properly processed canned clingstone peaches; not more than 5 percent by weight, of the drained clingstone peaches may be excessively frayed or mushy; and the product is otherwise reasonably free from crushed units.

(3) *Whole.* The units possess a texture typical of mature, properly ripened, properly prepared, and properly processed canned clingstone peaches; the units are reasonably tender or the tenderness may be variable within the unit; the units may be slightly firm or slightly soft but are not mushy; and not more than 10 percent by count of the units may possess a fairly good character, except for mushy or "not tender" units. One unit in a container is permitted to possess such fairly good character if such unit exceeds the allowance of 10 percent, by count: Provided, That the appearance or eating quality, or both, is not affected materially by the character of such unit.

(d) *"C" classification.* Halves, quarters, slices, dice, whole, or mixed pieces of irregular sizes and shapes of canned clingstone peaches that possess a fairly good character may be given a score of 21 to 23 points. Canned clingstone peaches that fall into this classification shall not be graded above U.S. Grade C regardless of the total score for the product (this is a limiting rule). "Fairly good character" has the following meanings with respect to the following styles of canned clingstone peaches:

(1) *Halves, quarters, slices, and mixed pieces of irregular sizes and shapes.* The units possess a texture typical of

mature, properly prepared, and properly processed canned clingstone peaches which may be variable in fleshness but the texture is fairly fleshy; the units may be lacking uniformity of tenderness; the units may be frayed but not excessively frayed or may be soft; and not more than 10 percent, by weight, of the drained clingstone peaches may be mushy or units that are so firm as to be "not tender."

(2) *Dice.* The product generally possesses a texture typical of mature, properly prepared, and properly processed canned clingstone peaches; not more than 10 percent, by weight, of drained clingstone peaches may be excessively frayed or mushy or are so firm as to be "not tender;" and the product is otherwise fairly free from crushed units.

(3) *Whole.* The units possess a texture typical of mature, properly prepared, and properly processed canned clingstone peaches which may be variable; the units may be lacking uniformity of tenderness; the units may be markedly firm or markedly ragged or soft; and not more than 10 percent, by count, of the units may be mushy or so firm as to be "not tender." One unit in a container is permitted to be mushy or "not tender" if such unit exceeds the allowance of 10 percent, by count: Provided, That in all containers comprising the sample, such units do not exceed an average of 10 percent of the total number of units.

(e) *"D" classification.* Canned clingstone peaches of any style that meet the requirements of paragraph (d) of this section with respect to units that are so firm as to be "not tender" but which otherwise possess a noticeably variable texture with not more than 25 percent, by weight, of the drained canned clingstone peaches that consist of mushy fruit may be given a score of 0 to 20 points and shall not be graded above U.S. Grade D, regardless of the total score for the product (this is a limiting rule).

(f) *"SStd" classification.* Canned clingstone peaches of any style that fail to meet the applicable requirements of paragraph (d) or (e) of this section may be given a score of 0 to 20 points and shall not be graded above standards, regardless of the total score for the product (this is a limiting rule). Halves, quarters, slices, dice, whole, or mixed pieces of irregular sizes and shapes of canned clingstone peaches that are "not tender" are also "Below Standard in Quality—Not Tender."

(g) *"C-SP" classification.* Halves, quarters, slices, dice, or mixed pieces of irregular sizes and shapes of canned "solid-pack" clingstone peaches that

possess a fairly good character for canned "solid-pack" clingstone peaches may be given a score of 21 to 23 points. Canned "solid-pack" clingstone peaches that fall into this classification shall not be graded above U.S. Grade C Solid-Pack regardless of the total score for the product (this is a limiting rule). "Fairly good character for canned 'solid-pack' clingstone peaches" means the product generally possesses a texture of properly prepared and properly processed "solid-pack" clingstone peaches which may be variable in tenderness, may be soft, or may consist of fairly firm units.

(h) *"SSStd-SP" classification.* Halves, quarters, slices, dice, or mixed pieces of irregular sizes and shapes of canned "solid-pack" clingstone peaches that fail to meet the requirements of paragraph (g) of this section may be given a score of 0 to 20 points and shall not be graded above substandard solid-pack, regardless of the total score for the product (this is a limiting rule).

4. In Part 52, § 52.2576 is added to read as follows:

§ 52.2576 Ascertaining the grade of a lot

The grade of a lot of canned clingstone peaches covered by these standards is determined by the procedures set forth in the regulations governing inspection and certification of processed fruits and vegetables, processed products thereof, and certain other processed food products (7 CFR 52.1 to 52.87).

(Agricultural Marketing Act of 1946, Secs. 203, 205, 60 Stat. 1087, 1090, as amended (7 U.S.C. 1622, 1624))

Dated: April 12, 1985.

William T. Manley,
Deputy Administrator, Marketing Programs.
[FR Doc. 85-9186 Filed 4-16-85; 8:45 am]
BILLING CODE 3410-02-M

Animal and Plant Health Inspection Service

9 CFR Parts 71 and 78

[Docket No. 83-089]

Individual Identification Devices for Cattle and Swine

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the regulations in 9 CFR Parts 71 and 78 for the purpose of requiring that certain individual identification devices remain on cattle and swine while such animals are being moved in interstate

commerce, from the point of origin of the interstate movement to final destination. The current regulations require that the devices remain on the animals only for the movement interstate. The adoption of the proposal would require that the devices remain on such animals from the point of origin of the interstate movement to final destination if such animals are being moved in interstate commerce. It appears that the adoption of the proposal would strengthen the tools available for use against the spread of communicable diseases of cattle and swine by helping establish a more effective means of tracing infected and exposed animals.

DATE: Written comments must be received on or before June 17, 1985.

ADDRESS: Written comments concerning this proposed rule should be submitted to Thomas O. Gessel, Director, Regulatory Coordination Staff, APHIS, USDA, Room 728, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Written comments received may be inspected at Room 728 of the Federal Building between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. Robert E. Wagner, VS, APHIS, USDA, Room 805, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-8684.

SUPPLEMENTARY INFORMATION:

Background

This document proposes to amend the "General Provisions" regulations and the "Brucellosis" regulations (contained in 9 CFR Parts 71 and 78 and referred to below as the regulations) by making changes concerning individual identification devices.

Interstate Movement and Interstate Commerce

Under the provisions of §§ 71.18 and 78.30 of the regulations, certain cattle and swine are required to be identified by backtags, ear tags, brands, or tattoos at the time of interstate movement of the animals. These individual identification devices are necessary as a tool for helping to trace the interstate spread of communicable animal diseases. For example, they can help identify the source of diseases by allowing an animal found to be infected with a disease to be traced back through marketing channels to the herd of origin, and to determine the extent of spread of a disease from the source by allowing animals to be traced from the herd of origin to the final destination. The animals can be traced by examining transaction records kept by owners,

market agencies, dealers, government agencies, and others. These records identify each animal by an individual identification device number or brand. The provisions in §§ 71.17 and 78.30 require that the individual identification devices remain on the animal only for the movement interstate. In many cases the person shipping the animals merely intends that they be shipped interstate to a stockyard or other place short of the final destination. Further, individual identification devices are sometimes replaced or altered during movement in marketing channels prior to the animals reaching their final destination. This can frustrate the purpose of the individual identification device. For example, if an animal found infected with a communicable disease does not have any individual identification or has inaccurate identification, it may be impossible to trace its movement back to its herd of origin and a possible foci of infection.

There is authority in the animal quarantine laws to require that individual identification devices on animals remain on the animals while they are being moved in interstate commerce. Utilization of this authority would mean that the devices would be required to remain on the animals while such animals are being moved from the point of origin interstate to the animals' final destination, such as a slaughtering establishment or a farm for breeding or raising. The movement in interstate commerce would include any temporary stops prior to movement to final destination, such as stops at a stockyard or dealer premises for feed, water, rest, or sale. In order for tracing to be effective, it appears that it is necessary to amend §§ 71.18 and 78.30 to require that such identification remain on the animals while they are being moved in interstate commerce.

Except for animals moved for slaughter, such identification would also likely allow the tracing of an animal for an extended period of time after movement in interstate commerce since the records that are kept concerning the movement of animals are usually kept for at least one year and it is customary practice for livestock owners on farms or ranches to leave such identification on the animals indefinitely.

Consistent with the discussion above, a definition of "moved (movement) in interstate commerce" would be added to §§ 71.1 and 78.1 to read as follows:

Moved from the point of origin of the interstate movement to the animal's final destination, such as a slaughtering establishment or a farm for breeding or raising, and including any temporary stops for any purpose prior to movement to final

destination, such as stops at a stockyard or dealer premises for feed, water, rest, or sale.

Removal or Tampering

In addition, §§ 71.18 and 78.30 of the regulations contain certain provisions concerning who is responsible for the identification of the animals in question and contain provisions concerning the removal of or tampering with the individual identification devices. In this connection, § 71.18(a)(3) provides:

Each person who ships, transports, or otherwise causes the movement of the cattle interstate is responsible for the identification of the animals as required by this section. No such person shall remove or tamper with or cause the removal of or tampering with an identification backtag or ear tag required in this section for interstate movement of animals, except as authorized by the Deputy Administrator, Veterinary Services, upon request in specific cases and under such conditions as he may impose to insure continuing identification.

Also, § 78.30(c) provides:

Each person who causes the movement of the swine interstate is responsible for the identification of the animals as required by this section. No such person shall remove or tamper with or cause the removal of or tampering with an identification tattoo or approved swine identification tag⁹ required in this section for interstate movement of swine, except at the time of slaughter, or as may be authorized by the Deputy Administrator, Veterinary Services, upon request in specific cases and under such conditions as he may impose to insure continuing identification.

Consistent with the proposal to provide the individual identification devices remain on the animals while the animals are being moved in interstate commerce, it is also proposed to amend §§ 71.18(a)(3) and 78.30(c) to require that after application the individual identification devices not be removed or tampered with as long as the animals are being moved in interstate commerce.

As noted above, the quoted provisions in §§ 71.18(a)(3) and 78.30(c) currently specify that certain persons responsible for the identification of the animals are prohibited from removing or tampering with identification backtags or ear tags and identification swine tattoos or approved swine identification tags. It is proposed to amend the quoted provisions to require that the prohibition against removal of or tampering with such devices apply to all identification devices required by §§ 71.18 and 78.30 rather than only the devices specified. Further, it is proposed to amend the quoted provisions to require that such prohibited apply to all persons while the animals are being moved in interstate commerce rather than only to those

persons responsible for the identification of the animals. It appears to be necessary to make these changes since an effective tracing program could be frustrated if any of the devices were allowed to be removed or tampered with by anyone.

Also, as noted above, § 78.30(c) indicates that the individual identification devices are allowed to be removed at the time of slaughter; however, § 71.18(a)(3) does not contain similar language. The individual identification devices are removed from the carcasses at the time of slaughter; and it appears necessary to clarify § 71.18(a)(3) to also provide that the devices are allowed to be removed at the time of slaughter.

Responsibility for Identification

In addition, as noted above, § 71.18(a)(3) places responsibility for the identification of animals on "each person who ships, transports, or otherwise causes the movement" of the animals and § 78.30(c) places such responsibility on "each person who causes the movement of" the animals. These provisions are intended to place such responsibility on "each person who ships, transports, or otherwise causes the movement" of the animals. Therefore, it appears that it is necessary to clarify § 78.30(c) to specify that such responsibility is placed on each person who ships, transports, or otherwise causes the movement of the animals.

Miscellaneous

In addition, this document proposes to make certain nonsubstantive changes for purposes of clarity.

Executive Order 12291 and Regulatory Flexibility Act

This proposed rule is issued in conformance with Executive Order 12291 and has been determined to be not a "major rule." Based on information compiled by the Department, it has been determined that this proposed rule would not have a significant effect on the economy, would not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and would not have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The adoption of the proposal would not impose additional activities on the part of anybody since it would merely require that individual identification

devices, which are already required to be applied to certain animals, remain on such animals while the animals are being moved in interstate commerce, from the point of origin of the interstate movement to final destination.

Under the circumstances explained above, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

List of Subjects

9 CFR Part 71

Animal diseases, Livestock and livestock products, Quarantine, Transportation.

9 CFR Part 78

Animal diseases, Cattle, Hogs, Quarantine, Transportation, Brucellosis.

Accordingly, it is proposed to amend 9 CFR Parts 71 and 78 as follows:

PART 71—GENERAL PROVISIONS

1. A new paragraph (p) would be added to § 71.1 to read as follows:

§ 71.1 Definitions.

(p) *Moved (movement) in interstate commerce.* Moved from the point of origin of the interstate movement of the animals' final destination, such as a slaughtering establishment or a farm for breeding or raising, and including any temporary stops for any purpose prior to movement to final destination, such as stops at a stockyard or dealer premises for feed, water, rest, or sale.

2. The heading for § 71.18 would be revised to read:

§ 71.18 Individual identification of certain cattle 2 years of age or over for movement in interstate commerce.

3. In the first sentence of § 71.18(a), "being moved interstate" would be changed to "being moved in interstate commerce" and "shall be moved interstate" would be changed to "shall be moved in interstate commerce".

4. In the second sentence of § 71.18(a), "All interstate movements" would be changed to "Any movement in interstate commerce."

5. In § 71.18(a)(1)(i), "May be moved interstate" would be changed to "May be moved in interstate commerce"; "when moved interstate," would be changed to "when moved in interstate commerce,"; and "such cattle are accompanied" would be changed to "such cattle when moved interstate are accompanied".

6. In § 71.18(a)(1)(ii), "May be moved interstate" would be changed to "May be moved in interstate commerce".

7. In the first proviso of § 71.18(a)(1)(ii), "if such cattle are moved interstate" would be changed to "if such cattle are moved in interstate commerce" and "when moved interstate," would be changed to "when moved in interstate commerce,".

8. In the second proviso of § 71.18(a)(1)(ii), "when such cattle are moved interstate" would be changed to "when such cattle are moved in interstate commerce".

9. In § 71.18(a)(1)(iii), the material preceding the first colon would be revised to read: "May be moved in interstate commerce for any purpose other than slaughter if such cattle, when moved in interstate commerce, are identified by Animal and Plant Health Inspection Service-approved ear tags in lieu of backtags, and are accompanied when moved interstate by an owner's statement or other document" stating:

10. In the proviso in § 71.18(a)(1)(iii), "which are moved interstate" would be changed to "which are moved in interstate commerce".

11. In § 71.18, paragraph (a)(3) would be revised and paragraph (a)(4) would be added. (Paragraph (a)(3) would be divided into paragraphs (a)(3) and (a)(4)).

§ 71.18 Individual identification of certain cattle 2 years of age or over for movement in interstate commerce.

(a) * * *

(3) Each person who ships, transports, or otherwise causes the cattle to be moved in interstate commerce is responsible for the identification of the cattle as required by this section.

(4) No person shall remove or tamper with or cause the removal of or tampering with a backtag, ear tag, brand, or other identification device required to be on cattle pursuant to this section while such cattle are being moved in interstate commerce, except at the time of slaughter, or as may be authorized by the Deputy Administrator, Veterinary Services, upon request in specific cases and under such conditions as the Deputy Administrator, Veterinary Services, may impose to ensure continuing identification.

PART 78—BRUCELLOSIS

12. A new paragraph (iii) would be added to § 78.1 to read as follows:

§ 78.1 Definitions.

* * *

(iii) *Moved (movement) in interstate commerce.* Moved from the point of origin of the interstate movement to the animals' final destination, such as a slaughtering establishment or a farm for breeding or raising, and including any temporary stops for any purpose prior to movement to final destination, such as stops at a stockyard or dealer premises for feed, water, rest, or sale.

13. In the heading for Subpart E, in 9 CFR Part 78, the word "Interstate" would be removed.

14. In § 78.26 the words "or in interstate commerce" would be added immediately after the word "interstate".

15. In the first sentence of § 78.30(a) "sows and boars moved interstate" would be changed to "sows and boars moved in interstate commerce" and "prior to such interstate movement" would be changed to "prior to such movement in interstate commerce".

16. In the second sentence of § 78.30(a), "may be moved interstate," would be changed to "may be moved in interstate commerce".

17. In the first sentence of § 78.30(b), "all breeding swine moved interstate" would be changed to "all breeding swine moved in interstate commerce" and "prior to such interstate movement" would be changed to "prior to such movement in interstate commerce".

18. In § 78.30, paragraph (c) would be revised and paragraph (d) would be added. (Paragraph (c) would be divided into paragraphs (c) and (d)).

§ 78.30 Identification of sows and boars.

(c) Each person who ships, transports, or otherwise causes the swine to be moved in interstate commerce is responsible for the identification of the swine as required by this section.

(d) No person shall remove or tamper with a tattoo, approved swine identification tag, or other identification device required to be on swine pursuant to this section while such swine are being moved in interstate commerce, except at the time of slaughter, or as may be authorized by the Deputy Administrator upon request in specific cases and under such conditions as the Deputy Administrator may impose to ensure continuing identification.

Authority: Secs. 4-7, 23 Stat. 32, as amended; secs. 1, 2, and 3, 32 Stat. 791-792, as amended; secs. 1-4, 33 Stat. 1264, 1265, as amended; 41 Stat. 899, sec. 101(a), 58 Stat. 734, as amended, sec. 2, 65 Stat. 693, secs. 3 and 11, 76 Stat. 130 and 132; 21 U.S.C. 111-113, 114a, 114a-1, 115, 116, 117, 120-126, 134b, 134f, 7 CFR 2.17, 2.51, and 371.2(d).

Done at Washington, D.C., this 10th day of April 1985.

G. J. Fichtner,

Acting Deputy Administrator, Veterinary Services.

[FR Doc. 85-8995 Filed 4-16-85; 8:45 am]

BILLING CODE 3410-34-M

FEDERAL ELECTION COMMISSION

11 CFR Part 110

[Notice 1985-4]

Contribution and Expenditure Limitations and Prohibitions: Contributions by Persons and Multicandidate Political Committees

AGENCY: Federal Election Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission requests comments on the proposed revision of its regulations governing limitations on contributions by persons and multicandidate political committees at 11 CFR 110.1 and 110.2. These regulations implement 2 U.S.C. 441a(a) (1) and (2), provisions of the Federal Election Campaign Act of 1971, as amended ("the Act"), 2 U.S.C. 431 *et seq.* The proposed revisions are intended to clarify the scope of the contribution limitations prescribed by each section by addressing several issues which have arisen since the present regulations were promulgated in 1977. Further information on the proposed amendments is provided in the supplementary information which follows.

DATES: Comments must be received on or before May 17, 1985.

ADDRESSES: Comments should be made in writing and addressed to Ms. Susan E. Propper, Assistant General Counsel, 1325 K Street, NW., Washington, D.C. 20463.

FOR FURTHER INFORMATION CONTACT: Ms. Susan E. Propper, Assistant General Counsel, (202) 523-4143 or (800) 424-9530.

SUPPLEMENTARY INFORMATION: The primary purpose of the proposed amendments to 11 CFR 110.1 and 110.2 is to address several issues raised in the administration of these provisions since they were adopted in 1977. Through this Notice, the Commission is seeking comment on §§ 110.1 and 110.2 using several different approaches to present the issues. The Commission notes that with respect to some issues, specific results are proposed in the attached draft rules, although a variety of approaches are under consideration. The alternatives are set forth below for

public comment. Additionally, the Commission is initiating this rulemaking in order to solicit comments on several broader questions for which no specific regulatory language is proposed at this time. Possible approaches to the broader issues are summarized below for public consideration. Finally, the Commission is interested in receiving public comment on the current language of sections 110.1 and 110.2.

Current Language of Sections

Section 110.1 Contributions by persons other than multicandidate political committees.

Section 110.1(a) Scope.

The Commission proposes to retitle § 110.1 "Contributions by persons other than multicandidate political committees," and to provide a "Scope" paragraph to explain who is subject to the contribution limitations of this section. These changes are proposed in response to questions the Commission receives from time to time as to whether § 110.1 applies to multicandidate political committees or permits contributions by corporations and labor organizations. The Commission notes that this confusion arises from the inclusion of corporations and labor organizations in the definitions of "person" in 2 U.S.C. 431(11) and 11 CFR 100.10. Therefore, the Commission is publishing for public comment a new paragraph 110.1(a), entitled "Scope" which is designed to clarify that the limitations prescribed by this section apply only to contributions made by persons other than multicandidate political committees (which are covered under § 110.2) and other than entities which are prohibited from making contributions under 11 CFR 110.4, and 11 CFR Parts 114 and 115, such as foreign nationals, corporations, labor organizations and Federal contractors. As revised, § 110.1 would still apply to individuals, partnerships, unincorporated associations and political committees other than multicandidate political committees.

Section 110.1(b) Contributions to candidates.

1. Statutory limitation on contributions. Paragraph § 110.1(b) of the proposed regulations would continue to set forth the rules governing contributions to candidates that are currently contained in § 110.1(a). Thus, paragraph (b)(1) would restate the \$1,000 statutory limitation in present § 110.1(a)(1) for contributions to a candidate and his or her authorized political committees and agents with

respect to any election for Federal office.

2. *Designation of contributions for particular elections.* In the administration of the campaign financing laws the Commission has encountered problems because the Act establishes separate contribution limitations for primary and general elections. See 2 U.S.C. 431(1) and 441a(a)(1) and (2). These provisions require the Commission to determine for which election a contribution is made. In making this determination, the Commission relies on the contributor's written designation for a particular election. If the contribution is undesignated, the present rule states that the contribution is for the next election. 11 CFR 110.1(a)(2)(ii). Different problems have arisen with regard to designated and undesignated contributions. For example, a contribution may be designated for a primary election, caucus or convention but received after the date of that election. The current regulations provide that such contributions shall be made only to the extent that they do not exceed net debts outstanding from such election. 11 CFR 110.1(a)(2)(i). However, the present regulation does not indicate what should be done with such designated contributions if the recipient candidate or his committee has no outstanding primary debts. The Commission is considering whether to revise its rules to provide that the candidate or authorized committee must return or obtain a written redesignation of contributions to the extent that they exceed net debts outstanding. See proposed 11 CFR 110.1(b)(1)(i). Under this proposed rule, the redesignation may be for any other election but must result in excessive contributions for that election.

The Commission recently received a request for advice on this issue from Congressman Don Pease. See Advisory Opinion ("AO") 1984-32 1 Fed. Election Camp. Fin. Guide (CCH) § 5777 at 11,094 (Aug. 17, 1984). In response, the Commission stated that the Pease Committee must either "return the contribution to the contributor or . . . have the contributor designate in writing that the contribution is for the . . . general election . . ." *Id.* at 11,095. The Commission requests comments as to whether the regulations should provide a particular length of time within which the recipient must make a refund or obtain a redesignation, and whether 10 days, 30 days, or 60 days would be appropriate. The Commission notes that under 11 CFR 103.3(a) all receipts by a political committee must be deposited

within 10 days of the treasurer's receipt. Contributions which appear to be illegal may be deposited pending a determination as to their legality under 11 CFR 103.3(b). In revising § 110.1 the Commission wishes to avoid any apparent conflict with § 103.3.

Under the present rule, only designated contributions made after a primary election are limited by the amount of outstanding debts. The Commission is considering broadening this rule so that it would also apply to designated contributions received after a general election, runoff election, or special election. Thus, proposed § 110.1(b)(2)(i) would provide that contributions for one of these elections, if made after the date of the election, may be made only to the extent that there are either net debts outstanding from such election or may be designated for a different election. This rule also provides that any amounts exceeding net debts outstanding must be returned or redesignated, as discussed above.

3. *Net debts outstanding.* In the context of the designation problems discussed above, the issue arises as to whether a candidate or his authorized committee has outstanding debts from a primary election. The present regulation does not define the term "net debts outstanding".

In AO 1984-32 Congressman Pease asked the Commission how to calculate net debts outstanding. The Commission responded that in its view, net debts outstanding "means the difference between (i) the total of the committee's debts and obligations incurred with respect to the primary election and (ii) the total of the committee's cash on hand and receivable available to pay those debts and obligations as of the date that a contribution designated for the primary election is made." AO 1984-32 at 11,095. The Commission is now interested in receiving comments as to whether the new regulations should include this formula. Therefore, the draft amendments which follow propose a definition for net debts outstanding which is modeled after the language in AO 1984-32. See § 110.1(b)(3). The proposed definition contains fuller descriptions of cash on hand and amounts owed to the committee. The Commission also requests suggestions as to other items that should be figured into the calculation of net debts outstanding. For example, funds carried over from a previous election could be included. The formula could also take into account the fair market value of capital assets and other assets without requiring their liquidation. See e.g. 11 CFR 9034.5(b)(1) and (2).

The Commission recognizes the practical difficulties that can arise for campaigns if they are expected to determine the existence of a primary debt as of a particular date, such as the date on which they received the contribution or the date of the election. AO 1984-32 suggests that the calculation should use the date on which the contribution was "made". Though this date is also included in proposed § 110.1(b)(3)(iii), the Commission requests comments as to whether one of the alternatives is preferable. Additional problems concerning the determination of when a contribution is "made" and "received" are discussed below.

The Commission also seeks public comment on whether to permit committees receiving such designated contributions to deposit them until they can determine the existence of a debt. Compare 11 CFR 103.3. The recipient could note this situation on the appropriate report filed with the Commission. Another issue concerns the appropriate length of time that should be allowed for determining the existence of a debt. Possible time limits include ten or thirty days from either the date of receipt or the date of deposit, or the end of the reporting period. In this context the Commission notes that often designated contributions received after the primary may have been contributed in connection with a joint fundraiser for several candidates. Hence, it may take some time for the recipients to determine the financial status of their campaigns. As discussed above, the Commission also requests comments as to the total amount of time that should be allowed for recipients to return contributions or obtain their redesignation if the recipient did not have debts.

The Commission occasionally receives inquiries as to whether the present regulations permit candidates to incorporate their primary debts into their general election funds and to pay their primary election debts with contributions properly received for the general election. Accordingly, the Commission requests comments as to whether the revised regulations should be clarified to specifically permit this, and how such a rule would affect the contribution limitations for both elections.

The Commission recognizes that many of the foregoing difficulties in administering and enforcing the contribution limitations result from the statutory establishment of limits on a per election basis rather than an election cycle basis. With respect to designated contributions, the

Commission requests suggestions as to how to avoid the need to determine whether the recipient committee is in a deficit position. One approach would be to provide that whenever excess primary funds are transferred to the general election account, they will count towards the contributor's ceiling for general election contributions. The recipient committee would determine which primary contributions are transferred on a last-received-first-transferred basis. If the committee has no excess primary funds to transfer, it need not go through this procedure. This approach would reduce the advantage currently enjoyed by candidates who are unopposed in the primary. The Commission also requests comments on applying this approach to contributions designated for a general election which are transferred to the next election cycle. Another way to eliminate the net debts outstanding problem would be to permit designated contributions to be made for a primary or general election regardless of whether the recipient candidate or committee has outstanding debts for that election and regardless of whether the contribution is made before or after the election. The Commission requests comments on this approach and on other possible ways to avoid calculation of net debts outstanding.

4. Procedure for designating contributions. In the administration and enforcement of the Act, the Commission has encountered recurring problems regarding the methods by which contributions are designated for particular elections. The Commission wishes to ensure greater uniformity in the reporting of designated contributions by their recipients and those donors subject to the reporting requirements of the Act. To achieve this goal, the Commission is proposing new § 110.1(b)(4) which would provide that designations must be indicated on the negotiable instrument comprising the contribution or in an attached or accompanying writing signed by the contributor. This new provision would require the written designation to be contemporaneous with the making of the contribution. This would ensure the communication of the designation to the recipient candidate or committee. Thus, the fact that a contributor has attempted to designate a contribution for a particular election in its reports filed with the Commission would not suffice for purposes of effecting a written designation under proposed § 110.1(b)(4).

The Commission recognizes that proposed § 110.1(b)(4), by requiring contemporaneous designations, would

preclude recipients from obtaining after-the-fact written designations or redesignations of contributions that appear to be excessive when received. Yet, written redesignations would be permitted under § 110.1(b)(2)(i) in the situation where the contribution is originally designated for a previously held election for which there are no outstanding debts. Accordingly, the Commission requests comments as to whether redesignation should be allowed at all, and if so, under what circumstances.

5. Determining when a contribution is made and who is an agent. The Commission has encountered several recurring problems with regard to undesignated contributions. Under the present rule, the determination as to whether an undesignated contribution counts against the contributor's limit for the primary or general election depends on when the contribution is "made." See 11 CFR 110.1(a)(2)(ii). However, the regulations do not define when a contribution is made. A question as to when a contribution is made can also arise when designated contributions are received after the date of the election designated. The Commission has also, encountered problems with regard to when contributions are "received." Recipients are required to report the date of receipt under 11 CFR 104.3 and 104.8, but "receipt" is left undefined. Moreover, in establishing date of receipt, questions may arise as to who is an agent of the recipient committee for the purposes of receiving contributions on its behalf. Accordingly, the Commission requests comments as to whether the terms "made," "received" and "agent" should be defined, and if so, what to include in the definitions.

Though the attached proposed rules do not contain draft definitions for these terms, the Commission nonetheless requests comments on several alternatives. For example, the regulations could state that the contribution is made on the date that the contributor relinquishes control over it, whether by mailing it or hand delivering it. However, this definition could result in the contributor reporting that the contribution was made on a date prior to the date on which the recipient would report having received the contribution. Recipient committees are required to report the date of receipt under 11 CFR 104.3 and 104.8. If the contributor and the recipient report different dates that do not fall within the same reporting period or that straddle an election, there is a problem in determining the appropriate election to which contributions should be attributed. This

might necessitate weighing additional evidence provided by the contributor or the recipient in substantiating their claims. This problem would not arise if the regulation, instead, provided that the contribution is made on the date it is received by the candidate or committee. Though a single date would result in greater uniformity in reporting, it nonetheless ignores the statutory distinction between making and receiving or accepting illegal contributions. *Cf. United States v. Hankin*, 607 F.2d 611 (3d Cir. 1979). Further, in the case of a contribution sent by mail or through an intermediary, it would be difficult for the contributor to ascertain the appropriate date to be reported. Of course, the contributor could avoid this problem simply by designating the contribution. Alternatively, the regulations could state that a contribution shall be considered to be made on the date that appears on the negotiable instrument. This date has the advantage of being readily ascertainable by all parties but has the disadvantage of possibly encouraging predating or post dating of checks. Moreover, checks are often not delivered on the same date they are written. Finally the regulations could provide that the date the contribution is made is the date it is deposited by the recipient. This alternative would give the recipient considerable latitude in determining when contributions are made. The Commission notes that in *United States v. Hankin*, 607 F.2d 611, 615 (3d Cir. 1979) the Third Circuit held that for the purposes of the Act's statute of limitations and given the circumstances of that case, certain contributions were made prior to the day on which they were deposited. This decision noted the statutory distinction between making and accepting illegal contributions. *Id.* at 613. The Court also cited the inclusion of pledges in the statutory definitions of "contribution." *Id.* at 614. It should be noted that after this case was decided, Congress amended the statutory definition of contribution to exclude contracts, promises or agreements to make contributions, whether or not legally enforceable.

As noted above, the question of when a contribution is made is related to the questions of when it is received and who has received it on behalf of the recipient committee. Hence it may be advisable to define who is an agent of a committee for the purpose of receiving contributions on its behalf. Therefore, the Commission welcomes suggestions as to whether to define "agent" and if so, what to include in the definition. As

an alternative, the revised rules could simply provide examples of situations in which an agency relationship would exist.

Section 110.1(c) Contributions to political party committees.

Section 110.1(b) of the present regulations restates the statutory limitation of \$20,000 for contributions to political committees established and maintained by national political parties. This provision would not be substantially modified under the proposed rules, but would be redesignated as § 110.1(c). However, the proposed rules would clarify that the national committee of a political party may receive contributions up to the \$20,000 limit even if it is the authorized committee of a Presidential candidate under 11 CFR 9002.1.

Section 110.1(d) Contributions to other political committees.

The proposed regulations would combine current paragraphs (c) and (d) into new paragraph (d) which would govern contributions to other political committees, including those making independent expenditures under 11 CFR Part 109.

Section 110.1(e) Contributions by partnerships.

A number of questions have arisen regarding § 110.1(e), which governs contributions by partnerships. This rule requires contributions by a partnership to be attributed to both the partnership and to the individual partners. This provision avoids creating the opportunity for members of partnerships to evade their individual contribution limitations. However, it has been suggested that the attribution rule is unnecessary for large partnerships because the amount attributed to individual partners may be nominal. Accordingly, the Commission requests suggestions for alternatives that would prevent evasion of the contribution limitations without imposing unnecessary requirements on large partnerships. Should the Commission decide to retain the present attribution rule, it is considering clarifying that the contribution counts against the limits for both the partnership and the individual partners. However, no portion of the contribution may be attributed to the corporate partners. An alternative approach would be to eliminate the limitation on partnership contributions and to attribute these contributions only to the individual partners.

The Commission recognizes that a number of partnerships have established plans in order to facilitate the making of

political contributions by members of the partnership. Accordingly, the Commission requests comments as to whether, as a result of such plans, these partnerships should be considered to be conduits or intermediaries subject to the requirements of 11 CFR 110.6 or to be political committees if they otherwise meet the definition of a political committee.

The Commission also requests comments concerning nonconnected political committees consisting of contributors who are partners of a particular partnership. In particular, comments are requested as to whether to permit such partnerships to institute check off systems whereby noncorporate partners and employees of corporate partners may authorize the partnership to withhold amounts from their shares of the profits or salaries and to forward such contributions directly to the partnership political action committee. The Commission is concerned that part of the administrative expenses incurred in running the checkoff system would be attributed, inevitably, to the corporate partners. The Commission also requests comments as to whether such a system would result in excessive contributions by the partnership to the nonconnected political committee. Such a checkoff system was approved in AO 1982-63, 1 Fed. Election Camp. Guide (CCH) §5704 at 10,948 (Feb. 10, 1983).

Section 110.1(f) Contributions to candidates for more than one federal office.

Section 110.1(f) of the proposed rules follows the current regulations as to the conditions under which a single contributor may donate up to \$1,000 for each election for each office if a candidate is running for more than one office. In this context, the Commission has received inquiries as to the application of paragraph (f), where, for example, a candidate receives contributions for a House race, then declares his candidacy for the Senate, but subsequently abandons his Senate bid and wishes to renew fundraising for his House campaign. See e.g., AO 1984-38 1 Fed. Election Camp. Guide (CCH) § 5780 at 11,098 (Aug. 22, 1984). Proposed § 110.1(f) is intended to clarify that a candidate's principal campaign committee or other authorized committee for one election to one office may not make transfers to, loans to, contributions to or expenditures on behalf of that candidate's other committees for his or her election to another office if such transaction would contain contributions which would be in violation of the Act.

Section 110.1(g) Contributions to retire debts.

Paragraph 110.1(g), governing contributions made to retire debts, would not be substantively amended under the proposed revisions.

Section 110.1(h) Aggregation of contributions.

The rules proposed today would make several modifications to § 110.1(h). These amendments are intended to clarify that contributions made to a particular candidate and his or her authorized committee must be aggregated with contributions made to unauthorized political committees for the purposes of the contribution limitations under certain circumstances. Such aggregation is designed to protect the contribution limitations when authorized committees seek contributions to support a candidate or a contribution earmarks a contribution made to an unauthorized committee for a particular candidate. The Commission requests comments as to whether this purpose is more clearly conveyed by the current wording of § 110.1(h) or by the new language. Under either version of paragraph (h), such aggregation would occur in any one of three situations. Hence, the "and" in present § 110.1(h) would be changed to "or" in the revised provision. The order in which the contributions are made does not affect the required aggregation. As under the current regulations, revised paragraphs (h)(1) and (h)(3) would govern situations when the recipient political committee is a principal campaign committee, authorized committee, or single candidate committee or when the contributor retains control over the funds.

Proposed paragraph (h)(2) would provide indicia of a contributor's "knowledge or belief" that a contribution will in turn be contributed to or expended on behalf of a particular candidate. As drafted, paragraph (h)(2) would also clarify that it even applies to contributions to a political committee which supports a candidate by making only independent expenditures on his or her behalf. This issue was specifically addressed in AO 1976-20 1 Fed. Election Campaign Guide (CCH) §6014 at 17,014 (Aug. 17, 1976), requested by Delaware Volunteers for Reagan. The Commission notes that the application of § 110.1(h) to contributions to committees making independent expenditures would not alter the circumstances under which political committees may make independent expenditures from the

funds they receive subject to the requirements of 11 CFR Part 109.

The Commission has also considered the question of whether § 110.1(h) applies to contributions made to a multicandidate political committee which makes representations to the contributor that a substantial portion of his or her contribution will be contributed to or expended on behalf of a particular candidate. See AO 1984-2 1 Fed. Election Camp. Guide (CCH) ¶5748 at 11,032 (Feb. 13, 1984). The proposed regulations would clarify that such contributions to multicandidate committees are subject to aggregation under § 110.1(h).

Section 110.1(i) Contributions by spouses and minors.

Several questions have arisen as to the making of joint contributions by spouses. The Commission has stated that both spouses "must sign either the instrument or an accompanying writing specifying that each is a contributor and the amount to be attributed to each." AO 1980-67, 1 Fed. Election Camp. Guide (CCH) ¶5527 at 10,621 (Aug. 12, 1980). The proposed rules would not alter the requirement of both signatures on joint contributions. See proposed 11 CFR 110.1(k).

Paragraph 110.1(i) was promulgated to permit both spouses in a single income family to make contributions to candidates. The Commission now requests comments as to whether § 110.1(i)(1) should be deleted because it does not add anything. Should the Commission decide to eliminate § 110.1(i)(1), contributions by both spouses in a single income family would still be allowable. Alternatively, the Commission requests comments on expanding § 110.1(i)(1) to include contributions to political committees. Similarly, the Commission is considering revising § 110.1(i)(2) to permit contributions by minors to political committees. Finally, the Commission requests comments as to whether to clarify the reference to "the proceeds of a trust" for which the minor is a beneficiary. 11 CFR 110.1(i)(2)(ii). "Assets" or "income" could be substituted for "proceeds."

Section 110.1(j) Contribution limitations for certain elections.

Paragraph 110.1(j), as revised, would retain the current rules regarding the types of elections that may be considered to be separate elections for purposes of the contribution limitations of this section. A cross reference to the definition of "election" at 11 CFR 100.2 would be included in § 110.1(j)(1) under the proposed regulations. This proposed

amendment is intended to clarify that, generally, there is a separate contribution limit for each general, primary, runoff, or special election and for a caucus or convention that qualifies as an election for purposes of the Act.

The Commission recently received an advisory opinion request that indirectly raised the issue of whether a general election which is not held because a candidate received a majority of votes in a primary election is nevertheless a separate election for the purposes of the contribution limitations. See AO 1984-54 1 Fed. Election Camp. Guide (CCH) ¶ 5794 at 11,127 (Nov. 13, 1984). Specifically, the treasurer of Representative Bob Livingston's principal campaign committee asked whether pre- and post-election reports need be filed where no general election for members of Congress was held in Louisiana on November 6, 1984. The Commission replied that such reports were required and that Representative Livingston was permitted to accept otherwise lawful contributions for the November general election in which he did not participate. Section 110.1(j)(3), as redrafted, would be broadened to follow this decision. The Commission therefore requests comments as to whether this result, or its opposite, should be expressly stated in the revised rules.

The Commission is also considering redrafting the corresponding reporting regulation to clarify whether pre- and post-election reports must be filed for a general election in which the candidate did not participate. See 11 CFR 104.5(a). For example, if the Commission ultimately decides against a separate contribution limitation, § 104.5 could be revised to clarify that pre- and post-election reports need not be filed for that general election. On the other hand, if the Commission decides to follow the result in AO 1984-54, then it should be apparent that reports must be filed under the present wording of § 104.5(a). However, this provision could nevertheless be revised to remove any uncertainty on this point. Therefore, the Commission requests comments as to which of these alternatives should be adopted with respect to § 104.5. However, the Commission does not intend to undertake a more extensive review or revision of § 104.5 in connection with this notice.

A similar problem arises when a primary election is not held under State law because a candidate was selected by a caucus or convention with authority to nominate a candidate. Under these circumstances, the Commission has decided that the candidate may receive contributions for the caucus or convention that nominated

the candidate but not for the primary election. See AO 1982-49 1 Fed. Election Camp. Guide (CCH) ¶5693 at 10,922 (OCT. 8, 1982). Proposed § 110.1(j)(4) would formalize this result. However, the Commission is interested in receiving comments as to whether the regulation should expressly follow this result or its opposite.

Section 110.1(k) Attribution of joint contributions.

Proposed § 110.1(k) is intended to suggest a possible approach to some problems which have arisen with regard to joint contributions. The proposed rule would continue the present requirement that all contributors sign the joint contribution. Frequently, the recipients of contributions drawn on joint accounts may not know how much should be attributed to each contributor. The proposed rule would, therefore, require that a written attribution accompany the contribution. In the present draft, however, this written attribution would not be required for contributions by spouses. Instead, the recipient may presume that one half of the contribution is attributable to each spouse in the absence of a statement to the contrary. The Commission requests comments on this provision and also on whether to extend the presumption of equal contributions to any contribution drawn on a joint account. The Commission notes that a similar provision is currently located in 11 CFR 104.8(d). It would be placed in 11 CFR 110.1, instead, because Part 104 primarily concerns reporting requirements.

Section 110.2 Contributions by multicandidate political committees.

Many of the problems regarding contributions by persons under § 110.1 also arise with regard to contributions by multicandidate committees under § 110.2. Therefore, proposed § 110.2 would generally follow the solutions suggested above for § 110.1. However, the Commission welcomes comments that suggest reasons for adopting different approaches in sections 110.1 and 110.2. In addition, the Commission requests comments as to whether the format of present § 110.2 should be reorganized to more closely parallel the format of § 110.1. For example, proposed § 110.2(a) would provide a new "Scope" paragraph which would state that this section applies to contributions made by multicandidate committees as defined at 11 CFR 100.5(e)(3). This follows current § 110.2(b).

The proposed rules would also separate the various limitations on

contributions by multicandidate committees presently contained in § 110.2(a) into separate sections. Thus, § 110.2(b) would set forth the limitations on contributions to candidates made by multicandidate committees. Paragraphs (b)(2) and (b)(3) of this proposed section would provide that the terms "with respect to any election" and "net debts outstanding" have the same meanings as in proposed § 110.1. Similarly, proposed paragraph (b)(4) would follow proposed § 110.1(b)(4) regarding acceptable methods for designating a contribution for a particular election. Proposed § 110.2(c) would state the \$15,000 limitation on contributions by multicandidate committees to political committees established and maintained by a national political party. Paragraph (d) would contain the limitation on contributions to other political committees by multicandidate committees and would provide that this limitation applies to contributions by committees making independent expenditures.

Proposed § 110.2(e) would follow § 110.2(c) of the present regulations to prescribe special limitations on contributions by the Republican and Democratic senatorial campaign committees to senatorial candidates in accordance with 2 U.S.C. 441a(h). The second sentence of this paragraph would be revised for clarity and consistency.

The proposed regulations would also include several new provisions in § 110.2 based on current § 110.1 (f), (g), and (h). These paragraphs govern contributions by multicandidate political committees to candidates for more than one Federal office, to retire debts, and to political committees supporting the same candidate. The current regulations do not state whether these sections apply to contributions by multicandidate political committees. Inclusion of these provisions is intended to clarify that these rules do apply to contributions made by multicandidate committees.

Proposed § 110.2(i) would explain which types of elections are separate elections for purposes of the contribution limitations of this section. This paragraph is largely based on current § 110.2(d). The changes in this provision would be identical to those which would be made to proposed § 110.1(j).

The Commission welcomes comments on the foregoing proposed amendments to 11 CFR 110.1 and 110.2, and the issues raised by this notice.

Statutory Authority

11 CFR Part 110; 2 U.S.C. 438(a)(8), 441a.

List of Subjects in 11 CFR Part 110

Campaign funds, Elections, Political candidates, Political committees and parties.

Certification of No Effect Pursuant to 5 U.S.C. 605(b) [Regulatory Flexibility Act].

The attached proposed rules, if promulgated, will not have a significant economic impact on a substantial number of small entities. The basis for this certification is that the primary purpose of the proposed revision is to clarify the Commission's rules governing limitations on contributions to political committees and candidates. This does not impose any significant economic burden because any entities affected are already required to comply with the Act's contribution limitations.

It is proposed to amend 11 CFR Part 110 as follows:

1. By revising 11 CFR 110.1 to read as follows:

§ 110.1 Contributions by persons other than multicandidate political committees (2 U.S.C. 441a(a)(1)).

(a) *Scope.* This section applies to all contributions made by any person as defined in 11 CFR 100.10, except multicandidate political committees as defined in 11 CFR 100.5(e)(3) or entities and individuals prohibited from making contributions under 11 CFR 110.4 and 11 CFR Parts 114 and 115.

(b) *Contributions to candidates.* (1) No person shall make contributions to any candidate, his or her authorized political committees or agents with respect to any election for Federal office which, in the aggregate, exceed \$1,000.

(2) For purposes of this section, "with respect to any elections" means—

(i) In the case of a contribution designated in writing by the contributor for a particular election, the election so designated except that a contribution designated in writing for a particular election, whether primary election, general election, runoff election caucus or convention, or special election as defined in 11 CFR 110.2 (b)-(f), but made after that election, shall be made only to the extent that the contribution does not exceed net debts outstanding from such election. To the extent that such contribution exceeds net debts outstanding, the candidate or the candidate's authorized political committee shall within 10 days so notify the contributor and shall—

(A) Return the contribution to the contributor, or

(B) Obtain written redesignation by the contributor for another election but only to the extent that the applicable limitations on contributions made with

respect to such other election would not be exceeded by such redesignation of the contribution. A contribution redesignated for a previous election shall not exceed net debts outstanding from the election.

(ii) In the case of a contribution not designated in writing by the contributor for a particular election,

(A) The next primary election, caucus or convention if made on or before the date of such primary election, caucus or convention, but after the date of the last general election for that Federal office which precedes such primary election, caucus or convention, or

(B) The next general election if made on or before the date of such general election but after the date of the primary election which precedes such general election.

(3) For purposes of this section, "net debts outstanding" means the total amount of unpaid debts and obligations incurred with respect to an election less the sum of:

(i) The total cash on hand available to pay those debts and obligations, including currency, traveler's checks, certificates of deposit, treasury bills, and balance on deposit in state banks, federally chartered depository institutions (including a national bank), and depository institutions the deposits accounts of which are insured by the Federal Deposit Insurance Corporation, Federal Savings and Loan Insurance Corporations, or the National Credit Union Administration; and

(ii) The total amounts owed to the candidate or political committee in the form of credits, refunds of deposits, return, or receivables, or a commercially reasonable amount based on the collectibility of those credits, refunds, returns, or receivables.

(iii) Net debts outstanding shall be calculated as of the date the contribution is made.

(4) For purposes of this section, a contribution shall be considered to be designated in writing for a particular election if—

(i) The contribution is made by check, money order, or other negotiable instrument which clearly indicates the particular election with respect to which the contribution is made; or

(ii) The contribution is attached to or accompanied by a writing, signed by the contributor, which clearly indicates the particular election with respect to which the contribution is made.

(c) *Contributions to political party committees.* (1) No person shall make contributions to the political committee established and maintained by a national political party in any calendar

year, which, in the aggregate, exceed \$20,000.

(2) For purposes of this section, "political committees established and maintained by a national political party" means—

- (i) The national committee;
 - (ii) The House campaign committee; and
 - (iii) The Senate campaign committee.
- (3) Each recipient committee referred to in 11 CFR 110.1(c) (2) may receive up to the \$20,000 limitation from a contributor, but the limits of 11 CFR 110.5 shall also apply to contributions made by an individual.

(4) The recipient committee shall not be an authorized political committee of any candidate, except as provided in 11 CFR 9002.1(c).

(d) *Contributions to other political committees.* (1) No person shall make contributions to any other political committee in any calendar year which, in the aggregate, exceed \$5,000.

(2) The limitation on contributions of this paragraph also applies to contributions made to political committees making independent expenditures under 11 CFR Part 109.

(e) *Contributions by partnerships.* A contribution by a partnership shall—

(1) Be attributed to each partner in direct proportion to his or her share of the partnership profits, according to instructions which shall be provided by the partnership to the political committee or candidate; or

(2) Be attributed by agreement of the partners, as long as—

- (i) Only the profits of the partners to whom the contribution is attributed are reduced (or losses increased), and
- (ii) These partners' profits are reduced (or losses increased) in proportion to the contribution attributed to each of them; and

(3) Not exceed the limitations on contributions in paragraph (b), (c), and (d) of this section.

(f) *Contributions to candidates for more than one Federal office.* If an individual is a candidate for more than one Federal office, a person may make contributions which do not exceed \$1,000 to the candidate, or his or her authorized political committees for each election for each office, as long as—

(1) Each contribution is designated in writing by the contributor for a particular office;

(2) The candidate maintains separate campaign organizations, including separate principal campaign committees and separate accounts; and

(3) No principal campaign committee or other authorized political committee of that candidate for one election for one Federal office transfers funds to,

loans funds to, makes contributions to, or makes expenditures on behalf of another principal campaign committee or other authorized political committee of that candidate for another election for another Federal office, except as provided in 11 CFR 110.3(a) (2) (iv).

(g) *Contributions to retire debts.* (1) Contributions made to retire debts resulting from elections held prior to January 1, 1975 are not subject to the limitations of this Part 110, as long as contributions and solicitations to retire these debts are designated in writing and used for that purpose.

(2) Contributions made to retire debts resulting from elections held after December 31, 1974 are subject to the limitations of this Part 110.

(h) *Contributions to committees supporting the same candidate.* No person who makes contributions to a candidate or his or her authorized political committees with respect to any election for Federal office shall make contributions to a political committee which has supported or anticipates supporting such candidate for the same election which in the aggregate exceed the applicable limitations on contributions of this section if:

(1) The political committee is the candidate's principal campaign committee or other authorized political committee or a single candidate committee;

(2) The contributor knows or believes that a substantial portion of the contribution will be contributed to, or expended on behalf of, that candidate for the same election. This includes contributions to a multicandidate political committee and contributions to a political committee which has supported or anticipates supporting that candidate only by making independent expenditures on his or her behalf. Indicia of such knowledge or belief may include representations made by the political committee in the solicitation received by the contributor, and contributions which are in any way earmarked for a particular candidate; or

(3) The contributor retains control over the funds.

(i) *Contributions by spouses and minors.*

(1) The limitations on contributions of this section shall apply separately to contributions made by each spouse in a single income family.

(2) Minor children (children under 18 years of age) may make contributions to any candidate or political committee which in the aggregate do not exceed the limitations on contributions of this section, if—

(i) The decision to contribute is made knowingly and voluntarily by the minor child;

(ii) The funds, goods, or services contributed are owned or controlled exclusively by the minor child, such as income earned by the child, the proceeds of a trust for which the child is the beneficiary, or a savings account opened and maintained exclusively in the child's name; and

(iii) The contribution is not made from the proceeds of a gift, the purpose of which was to provide funds to be contributed, or is not in any other way controlled by another individual.

(j) *Application of limitations to elections.* (1) The limitations on contributions of this section shall apply separately with respect to each election as defined in 11 CFR 100.2, except that all elections held in a calendar year for the office of President of the United States (except a general election for that office) shall be considered to be one election.

(2) An election in which a candidate is unopposed is a separate election for the purposes of the limitations on contributions of this section.

(3) A primary or general election which is not held because a candidate is unopposed or received a majority of votes in a previous election is a separate election for the purposes of the limitations on contributions of this section. The date on which the election would have been held shall be considered to be the date of the election.

(4) A primary election which is not held because a candidate was nominated by a caucus or convention with authority to nominate is not a separate election for the purposes of the limitations on contributions of this section.

(k) *Attribution of contributions.* (1) Any contribution made by more than one person, except a contribution made by spouses, shall indicate on the check, money order, or other negotiable instrument, or in a contemporaneous writing signed by all contributors, the amount to be attributed to each contributor.

(2) If a contribution made by spouses does not indicate the amount to be attributed to each spouse, one half of the amount of the contribution shall be attributed to each spouse.

(3) Any contribution made by more than one person shall include the signature of each contributor on the check, money order, or other negotiable instrument or in a contemporaneous writing.

2. By revising 11 CFR 110.2 to read as follows:

§ 110.2 Contributions by multicandidate political committees (2 U.S.C. 441a(a)(2)).

(a) *Scope.* This section applies to all contributions made by any multicandidate political committee as defined in 11 CFR 100.5(e)(3).

(b) *Contributions to candidates.* (1) No multicandidate political committee shall make contributions to any candidate, his or her authorized political committees or agents with respect to any election for Federal office which, in the aggregate, exceed \$5,000.

(2) For purposes of this section, "with respect to any election" has the same meaning as in 11 CFR 110.1(b)(2).

(3) For purposes of this section, "net debts outstanding" has the same meaning as in 11 CFR 110.1(b)(3).

(4) For purposes of this section, a contribution shall be considered to be designated in writing for a particular election if the requirements set forth in 11 CFR 110.1(b)(4) (i) or (ii) are satisfied.

(c) *Contributions to political party committees.* (1) No multicandidate political committee shall make contributions to the political committees established and maintained by a national political party in any calendar year which, in the aggregate, exceed \$15,000.

(2) For purposes of this section, "political committees established and maintained by a national political party" means—

- (i) The national committee;
- (ii) The House campaign committee; and

(iii) The Senate campaign committee.

(3) Each recipient committee referred to in 11 CFR 110.2(c)(2) may receive up to the \$15,000 limitation from a multicandidate political committee.

(4) The recipient committee shall not be an authorized political committee of any candidate, except as provided in 11 CFR 9002.1(c).

(d) *Contributions to other political committees.* (1) No multicandidate political committee shall make contributions to any other political committee in any calendar year which, in the aggregate, exceed \$5,000.

(2) The limitation on contributions of this paragraph also applies to contributions made to political committees making independent expenditures under 11 CFR 109.

(e) *Contributions by political party committees to Senatorial candidates.* Notwithstanding any other provision of the Act, or of these regulations, the Republican and Democratic Senatorial campaign committees, or the national committee of a political party, may make contributions of not more than a combined total of \$17,500 to a candidate for nomination or election to the Senate

during the calendar year of the election for which he or she is a candidate. Any contribution made by such committee to a Senatorial candidate under this paragraph in a year other than the calendar year in which the election is held shall be considered to be made during the calendar year in which the election is held.

(f) *Contributions to candidates for more than one Federal office.* If an individual is a candidate for more than one Federal office, a multicandidate political committee may make contributions which do not exceed \$5,000 to the candidate, or his or her authorized political committees for each election for each office, provided that the requirements set forth in 11 CFR 110.1(f) (1), (2), and (3) are satisfied.

(g) *Contributions to retire debts.* (1) Contributions made to retire debts resulting from elections held prior to January 1, 1975 are not subject to the limitations of this Part 110, as long as contributions and solicitations to retire these debts are designated in writing and used for that purpose.

(2) Contributions made to retire debts resulting from elections held after December 31, 1974 are subject to the limitations of this Part 110.

(h) *Contributions to committees supporting the same candidate.* No multicandidate political committee which makes contributions to a candidate or his or her authorized political committees with respect to any election for Federal office shall make contributions to a political committee which has supported or anticipates supporting such candidate for the same election which in the aggregate exceed the applicable limitations on contributions of this section if:

(1) The political committee is the candidate's principal campaign committee or other authorized political committee or a single candidate committee;

(2) The multicandidate political committee or the treasurer of such committee knows or believes that a substantial portion of the contribution will be contributed to, or expended on behalf of, that candidate for the same election. This includes contributions to another multicandidate political committee and contributions to a political committee which has supported or anticipates supporting that candidate only by making independent expenditures on his or her behalf; or

(3) The multicandidate political committee retains control over the funds.

(i) *Application of limitations to elections.*

(1) The limitations on contributions of this section (other than paragraph (e) of this section) shall apply separately with respect to each election as defined in 11 CFR 100.2, except that all elections held in a calendar year for the office of President of the United States (except a general election for that office) shall be considered to be one election.

(2) An election in which a candidate is unopposed is a separate election for the purposes of the limitations on contributions of this election.

(3) A primary or general election which is not held because a candidate is unopposed or received a majority of votes in a previous election is a separate election for the purposes of the limitations on contributions of this section. The date on which the election would have been held shall be considered to be the date of the election.

(4) A primary election which is not held because a candidate was nominated by a caucus or convention with authority to nominate is not a separate election for the purposes of the limitations on contributions of this section.

Dated: April 11, 1985.

John Warren McGarry,
Chairman, Federal Election Commission,
[FR Doc. 85-9179 Filed 4-16-85; 8:45 am]
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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 225 and 277

[Docket Nos. RM80-8-001, RM80-8-002, RM80-8-003, RM80-8-004, and RM80-8-005]

Bona Fide Offers; Right of First Refusal; Notice of Extension of Time for Comments

April 12, 1985.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of request for additional comments; extension of comment period.

SUMMARY: On March 11, 1985, the Commission issued a Notice of Request for Additional Comments on issues raised by petitions for rehearing, reconsideration, and clarification of Order No. 95, concerning bona fide offers and right of first refusal (50 FR 10243, March 14, 1985). The comment period is being extended at the request of the Interstate Natural Gas Association of America.

DATE: Comments must be submitted on or before April 30, 1985.

ADDRESS: Submit comments to: Office of the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426.

FOR FURTHER INFORMATION CONTACT: Kenneth F. Plumb, Secretary, (202) 357-8400.

SUPPLEMENTARY INFORMATION:

Notice of Extension of Time

In the matter of Bona Fide Offer; Right of First Refusal; Docket Nos. RM80-8-001, RM80-8-002, RM80-8-003, RM80-8-004, and RM80-8-005.

April 12, 1985.

On April 8, 1985, the Interstate Natural Gas Association of America (INGAA) filed a motion for an extension of time to file comments in response to the Commission's Notice of Request for Additional Comments issued March 11, 1985, in the above-docketed proceeding. In its motion, INGAA states that it requires additional time because the association's staff and its member companies are involved in addressing numerous judicial and administrative matters pertaining to notices and orders issued in other pending Commission proceedings.

Upon consideration, notice is hereby given that an extension of time for the filing of comments is granted to and including April 30, 1985.

Kenneth F. Plumb,
Secretary.

[FR Doc. 85-9271 Filed 4-16-85; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 78P-0052]

Food Ingredient Labeling; Emulsifiers and Stabilizers; Exemptions

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) proposes to permit ingredients used as stabilizers and emulsifiers in food (e.g., carob bean gum, cellulose gum, lecithin) to be identified in the ingredient statement by the appropriate generic term "stabilizers" or "emulsifiers" and listed in the order of predominance of the total amount of stabilizers or emulsifiers. The specific common or

usual name of the ingredient would appear in parentheses following the generic term. FDA also is proposing that the stabilizer or emulsifier ingredients listed within parentheses be permitted to appear in other than descending order of predominance, and is proposing to allow the declaration of those stabilizing and emulsifying agents that may not always be present. This action responds to a petition filed by the National Association of Fruits, Flavors, and Syrups, Inc.

DATE: Comments by June 17, 1985.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFF-312), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-485-0177.

SUPPLEMENTARY INFORMATION: FDA received a petition from the National Association of Fruits, Flavors, and Syrups, Inc. (NAFFS) that requested that the food ingredient labeling regulations be revised to provide manufacturers using blends of stabilizers and emulsifiers with greater flexibility in formulating their products. Specifically, NAFFS requested that blends of stabilizers and/or emulsifiers be optionally declared in the ingredient list by a collective name such as "stabilizers and/or emulsifiers" with the individual stabilizers and emulsifiers listed in parentheses without respect to the order of predominance requirements of § 101.4 (21 CFR 101.4). In addition, the petition requested that FDA allow manufacturers to list in parentheses those stabilizers and emulsifiers which are used intermittently in the manufacture of a food even though all of the listed ingredients may not be present in the food.

Stabilizers (e.g., carob bean gum, cellulose gum, gum arabic) and emulsifiers (e.g., lecithin, monoglycerides and diglycerides, polysorbates) are present in many manufactured foods in small quantities (usually less than 3 percent of the total weight). They are added for technological functions such as establishing and maintaining emulsions.

NAFFS pointed out that many food manufacturers find it expedient to vary the stabilizers and emulsifiers used in a food according to manufacturing locality. Consequently, firms with manufacturing plants in various locations in the United States must either maintain numerous label stocks,

thereby increasing costs which will be passed on to the consumer, or sacrifice the advantages of local formulation and purchase the stabilizers and emulsifiers from one proprietary source. NAFFS contends that if such sacrifices are made, trade is restrained and technical progress is hampered. More localized firms are also adversely affected by the present regulations. These firms do not have the flexibility to purchase the most economical stabilizers and emulsifiers without maintaining numerous label stocks. In addition, NAFFS contended that stabilizers and emulsifiers should not have to be listed in descending order of predominance because (1) their amount in a food is normally less than 3 percent of the total weight of the food, (2) they are often used interchangeably in foods, and (3) the predominance of one stabilizer or emulsifier over another is of little importance to the consumer. Further, NAFFS stated that FDA has already established a precedent for the requested revisions by promulgating in 1976 similar revisions in the labeling regulations pertaining to fats and oils in § 101.4(b)(14).

FDA delayed action on the NAFFS petition to complete an evaluation of the views and comments received as a result of the 1978 food-labeling hearings (announced in 43 FR 25296, June 9, 1978), FDA's December 21, 1979 notice announcing its tentative positions on issues considered at these hearings (44 FR 75990; December 21, 1979), and the 1980 hearings on FDA's tentative positions (announced in 44 FR 75990; December 21, 1979).

Only a few comments received in response to the December 21, 1979 notice or during the 1978 and 1980 food-labeling hearings pertain directly to the NAFFS petition. These comments, all from industry, endorsed the types of ingredient labeling exemptions requested by NAFFS and stated that food costs would rise unnecessarily without these exemptions.

Other comments indirectly pertain and take a position contrary to the NAFFS petition. Many of these comments, primarily from consumers, requested more, rather than less, food-labeling information. Also, many consumers who stressed the importance of avoiding certain ingredients for health, religious, or other reasons objected to the use of "and/or" labeling to declare the source of fats and oils. Conversely, other comments confirm that many consumers are quite concerned about rising food costs. Some consumer comments suggested that less labeling information might be justified if food costs could be reduced. Few of the

consumers advocating more food labeling appeared to have considered the economic impact of additional labeling requirements.

In the past, where practicable, FDA has increased flexibility in ingredient labeling regulations in order to reduce manufacturing costs that would be otherwise passed on to the consumer. Executive Order 12291 clearly supports this policy by directing that regulatory relief to the public be provided to the extent permitted by law. The agency acknowledges that the NAFFS-requested exemptions are similar not only to exemptions already granted for fats and/or oils (§ 101.4(b)(14)), but also to those granted for leavening agents (§ 101.4(b)(16)), yeast nutrients (§ 101.4(b)(17)), dough conditioners (§ 101.4(b)(18)), and firming agents (§ 101.4(b)(19)).

The exemptions requested by NAFFS appear to be reasonable in those situations where the manufacturer is unable to adhere to a constant pattern of stabilizers and/or emulsifiers in the food. Exemptions appear to be unnecessary where these ingredients are constant. Accordingly, FDA is proposing to establish the requested exemptions, but to limit their applicability to situations where stabilizer and emulsifier use patterns do not remain constant.

Although NAFFS requested that the collective name "stabilizers and/or emulsifiers" be used for these exemptions, FDA believes that this use would be misleading in light of the differing functions of stabilizers and emulsifiers. FDA is not aware of any substance that is used as both a stabilizer and an emulsifier. Accordingly, the agency is proposing that ingredients within these categories be ground according to their function with the collective name "stabilizers" or "emulsifiers," as appropriate.

Ingredients used as stabilizers or emulsifiers are currently required to be listed in the ingredient statement along with other ingredients in descending order of predominance solely by their common or usual or chemical names, and are therefore not identified as stabilizers or emulsifiers. If the proposed exemption is adopted and a manufacturer elects to use it, these ingredients will be identified, in order of predominance, by the common or usual name in parenthesis following the collective term "stabilizers" or "emulsifiers." Additionally, if a manufacturer is unable to adhere to a constant pattern of stabilizers or emulsifiers in the food products, the listing of the individual stabilizers or emulsifiers need not be in descending

order of predominance as long as it follows identifying words such as "or", "and/or", or "contains one or more of the following:". FDA believes that the parenthetical information will provide consumers enough information to avoid the ingredients if desired. Consumers wanting to avoid a particular stabilizers or emulsifiers would have to avoid those foods that have labels indicating that the ingredient may be present because it is used interchangeably with another.

The agency believes that the concerns of both consumers and industry about rising food costs should not be ignored. If it grants the requested exemptions, manufacturers would not have to change their labels each time they use a different stabilizer or emulsifier. Under current regulations, this type of change requires a different label. Manufacturers would also be able to take advantage of price fluctuations of stabilizers or emulsifiers. The exemptions would enable manufacturers to purchase ingredients on the basis of price and availability, fostering competition in pricing. The net effect of these benefits to manufacturers would be to help keep their production costs down. These lower production costs should help keep down the price that consumers pay for the finished food.

In accordance with actions taken on similar exemptions pending issuance of a final regulation (see 47 FR 16347), FDA will not initiate regulatory action against any food product on the basis of improper ingredient declaration of stabilizers and emulsifiers, provided such ingredient declarations are in accordance with this proposal.

In accordance with Executive Order 12291, the economic effects of this proposal have been reviewed, and it has been determined that the proposed rule is not a major rule as defined by the Order. This proposal, if adopted, will provide an optional exemption for some foods containing stabilizers and/or emulsifiers from an existing mandatory requirement that each stabilizers and/or emulsifiers be listed in descending order of predominance. Manufacturers would therefore not be required to change existing labels, and they may be provided with greater flexibility in listing mandatory information on new labels. No increase in manufacturers' labeling costs is therefore expected.

FDA, in accordance with the Regulatory Flexibility Act (Pub. L. 96-354), has considered the effect this proposed rulemaking would have on small entities, including small businesses. Because the effect of this proposed regulation is to provide an optional exemption for some foods containing stabilizers and/or emulsifiers

from certain labeling requirements, the agency has determined that it may reduce labeling costs for all affected manufacturers. FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will result from the proposal, if adopted.

The agency has determined in accordance with 21 CFR 25.24(d)(13) (proposed December 11, 1979; 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Paperwork Reduction Act of 1980

This proposed rule modifies paragraph (b) of 21 CFR 101.4 that provides exemptions from the information collection requirement contained in paragraph (a) of § 101.4. FDA has submitted § 101.4(a) to the Office of Management and Budget (OMB) for its review as stipulated in 3 CFR 1320.14. The requirement has been approved and assigned OMB control number 0910-0200.

List of Subjects in 21 CFR Part 101

Food labeling, Misbranding, Nutrition labeling, Warning statements.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 403, 701(a), 52 Stat. 1047-1048 as amended, 1055 (21 U.S.C. 343, 371(a))) and under CFR 5.11, it is proposed that Part 101 be amended in § 101.4 by adding new paragraph (b)(23), to read as follows:

PART 101—FOOD LABELING

§ 101.4 Food; designation of ingredients

(b) * * *

(23) Ingredients that act as stabilizers or emulsifiers may be declared in the ingredient statement, in order of predominance appropriate for the total of all stabilizers or emulsifiers in the food, by stating the specific common or usual name of each stabilizer and emulsifier in descending order of predominance to parentheses following the collective name "stabilizers," or "emulsifiers," as appropriate, e.g., "stabilizers (carob bean gum, cellulose gum, gum arabic)." If the manufacturer is unable to adhere to a constant pattern of stabilizers or emulsifiers in the food, the listing of the individual stabilizers or emulsifier agents need not be in descending order of predominance. Stabilizers and emulsifiers not present

in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that may not be present, such as "or", "and/or", contains one or more of the following:"

Interested persons may, on or before June 17, 1985, submit to the Dockets Management Branch (address above), written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 18, 1985.

Frank E. Young,

Commissioner of Food and Drugs.

Margaret M. Heckler,

Secretary of Health and Human Services.

FR Doc. 85-9238 Filed 4-16-85; 8:45 am]

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

Docket No. H-225]

Occupational Exposure to Formaldehyde

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: This notice announces the initiation of the rulemaking process by OSHA with respect to reducing exposures to formaldehyde under section 6(b) of the Occupational Safety and Health Act of 1970 (the Act), 29 U.S.C. 655(b). This regulatory action occurs following a public meeting held by OSHA in Washington, D.C. on February 13-15, 1985, to collect information on the health effects and risks of exposure to formaldehyde. The notice summarizes information currently available to OSHA concerning production and use of formaldehyde, health effects, and estimates of employee exposure. The notice invites interested parties to submit data, views, and comments regarding OSHA's development of a new standard for formaldehyde and the appropriate scope of coverage.

DATE: Comments in response to this Advance Notice should be submitted by August 15, 1985.

ADDRESS: Comments should be submitted in quadruplicate to the Docket Officer, Occupational Safety and Health Administration, Docket No. H-225, Room N-3670, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20210.

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, Occupational Safety and Health Administration, U.S. Department of Labor, Office of Information, Room N-3641, Washington, D.C. 20210, Telephone (202) 523-8151.

SUPPLEMENTARY INFORMATION:

1. Introduction

The present occupational health standard for formaldehyde (CAS Registry No. 50-00-0) requires employers to assure that employee exposure to formaldehyde does not exceed 3 parts per million parts of air (3 ppm), determined as an 8-hour time-weighted average (TWA), 5 ppm as a ceiling concentration, and 10 ppm as a maximum peak for a total of up to 30 minutes during an 8-hour workshift. This standard is codified at 29 CFR 1910.1000, Table Z-2 and was adopted in 1971 pursuant to section 6(a) of the Act. The source of this standard was a national consensus standard developed in 1967 by the American National Standards Institute, Inc. (ANSI) [Ex.42-9].

In 1976, the National Institute for Occupational Safety and Health (NIOSH) transmitted a criteria document on occupational exposure to formaldehyde to OSHA. In this criteria document [Ex. 42-85], NIOSH recommended that formaldehyde be controlled so that no employee receives exposure at a concentration greater than 1.2 milligrams per cubic meter (1.2 mg/m³) (equivalent to 1 ppm) for any 30-minute sampling period. In addition, NIOSH included provisions for employee exposure monitoring and recordkeeping, medical surveillance, labeling, personal protective equipment, work practices and engineering controls, and training to inform employees of the hazards of exposure to formaldehyde. These recommendations for a reduction in the permissible exposure level and other protective requirements for formaldehyde were based on its irritant properties.

In October 1979, the Chemical Industry Institute of Toxicology (CIIT) sent preliminary findings of a carcinogenicity study which was being conducted at Battelle Columbus Laboratories to the Environmental Protection Agency (EPA) under

procedures established by the Toxic Substances Control Act (TSCA) for notification of substantial risk (section 8(e)). This notification (No. 79-314) indicated that squamous cell carcinoma of the nasal cavity had been observed at interim sacrifice in some rats exposed to formaldehyde at 14.3 ppm. When the study was completed in 1981, final results showed nasal cancers in rats exposed at 5.6 and 14.3 ppm and in mice exposed at 14.3 ppm [Ex. 12].

Based on its concerns about the potential for adverse effects from chronic exposure to formaldehyde, NIOSH published Current Intelligence Bulletin 34, "Formaldehyde—Evidence of Carcinogenicity" on April 15, 1981 [Ex. 42-86]. In this bulletin, NIOSH recommended that formaldehyde be handled in the workplace as a potential occupational carcinogen. This recommendation was based on the finding of cancer of the nasal cavities in experimental animals exposed by inhalation to formaldehyde.

In 1983, the American Conference of Governmental Industrial Hygienists (ACGIH) established a threshold limit value (TLV) of 1 ppm as an 8-hour TWA for formaldehyde and included this chemical on the list of industrial substances suspect of carcinogenic potential for man. The ACGIH list also includes a short-term exposure limit (STEL) of 2 ppm for formaldehyde [Ex. 42-8].

A number of other groups have evaluated available information on formaldehyde and published their conclusions. In 1982, the International Agency for Research on Cancer (IARC) concluded that although there was sufficient evidence that formaldehyde gas is carcinogenic to rats, epidemiological studies provided inadequate evidence to assess the carcinogenicity of formaldehyde in man [Ex. 42-70]. In its Third Annual Report of Carcinogens, published in September, 1983, the U.S. Department of Health and Human Services listed formaldehyde among the substances or groups of substances that may reasonably be anticipated to be carcinogens [Ex. 52]. On May 23, 1984, the EPA announced that two categories of formaldehyde exposures, that occurring from apparel manufacture and that associated with residence in manufactured housing, showed a potential for significant risk of widespread harm, which warranted designation for priority review under section 4(f) of TSCA. Action under section 4(f) is based on a substance's ability to induce cancer, gene mutations, or birth defects. EPA did not examine

the irritant properties of formaldehyde in reaching its conclusions [Ex. 42-41].

2. Petition for Emergency Temporary Standard (ETS)

On October 26, 1981, the United Automobile, Aerospace, and Agricultural Implement Workers of America (UAW), joined by 13 other unions, petitioned OSHA to issue an ETS which would impose a number of protective requirements for the handling of formaldehyde. On January 29, 1982, OSHA denied the request and the petitioners appealed the decision to the District Court of the District of Columbia. On July 2, 1984, the Court remanded the formaldehyde case to the Agency for reconsideration (*UAW v. Donovan*, 590 F. Supp. 747 (D.D.C. 1984)). The Court concluded, based on consideration of several factors involving the statutory framework and the posture of the case, that reappraisal by OSHA would be preferable to judicial review based on the record as it existed in January, 1982, when the ETS petition was denied. The Court observed that the issues surrounding the regulation of formaldehyde were much more sharply defined than they had been when the ETS petition was denied, citing as an example the accomplishments of the Consensus Workshop on Formaldehyde.

The Consensus Workshop on Formaldehyde convened on October 3-6, 1983, with the objective of developing general agreement on important controversies surrounding the scientific status of formaldehyde. Over 60 government, industry, university, and public interest organization scientists served on the following eight panels: (1) Exposure; (2) Epidemiology; (3) Carcinogenicity, Histopathology, Genotoxicity; (4) Immunology, Sensitization, Irritation; (5) Structure Activity, Biochemistry, Metabolism; (6) Reproduction, Teratology; (7) Behavior, Neurotoxicity, Psychological Effects; and (8) Risk Estimation. Each panel reviewed the major scientific studies relevant to its area and prepared a consensus report addressing discussion topics brought before the panel. The other seven panels supplied reports to the Risk Estimation Panel, the group charged with the task of determining how the data could be used to make reasonable risk estimates for humans exposed to formaldehyde at various levels and through different routes. A compilation of the panel reports has been prepared through the National Center for Toxicological Research and these deliberations were published recently in *Environmental Health Perspectives* [Ex. 70-56].

On November 5, 1984, OSHA's Office of Risk Assessment (ORA) submitted a report, Preliminary Assessment of the Health Effects of Formaldehyde (The ORA Report) [Ex. 43], which reviewed the health issues raised in the Court's remand order. This report relied heavily on a draft report of the Consensus Workshop [Ex. 42-30] in updating OSHA's information on formaldehyde. The ORA Report was distributed for peer review to members of OSHA's National Advisory Committee for Occupational Safety and Health and to certain government and industry scientists who had research or regulatory interests in formaldehyde. Several members of the public also volunteered comment on the ORA Report. These comments have been placed in the public record [Exs. 44-1 to 44-24, 45-1 to 45-7] and are available from the Docket Office upon request. Based on the entire record before the Agency, with particular emphasis on the new information presented in the ORA Report and in the peer review and public comments, OSHA again denied the petition for an ETS on formaldehyde on January 7, 1985 [Ex. 61].

3. Present Status of OSHA's Deliberation

The decision of the District Court directs OSHA to consider the UAW petition not only as a request for an ETS under section 6(c) of the Act, but also as a request for revision of the permanent standard for formaldehyde under section 6(b). OSHA's reply to the petitioners is due by April 15, 1985. Because of a recent court decision regarding subject matter jurisdiction, the formaldehyde case has been transferred to the U.S. Circuit Court of Appeals for the District of Columbia. However, the Circuit Court has indicated its intention to enforce the schedule imposed by the District Court (*UAW v. Donovan*, No. 85-1003, D.C. Circuit, March 5, 1985).

On January 11, 1985, OSHA announced that a public meeting would be held in Washington, D.C., on February 13-15, 1985 [50 FR 1547]. This meeting was designed to generate information and dialogue, which would help OSHA determine whether or not occupational exposure to formaldehyde constitutes a significant risk of material impairment of health. Final posthearing comments were due by March 8, 1985, and, at present, OSHA is evaluating the health data received in the course of this public meeting. OSHA's assessment of the health effects associated with exposure to formaldehyde indicates, at this point, that the existing occupational health standard is inadequate.

Simultaneously, OSHA has been examining information on current conditions in the formaldehyde industry and available control technology to determine what exposure levels are technologically and economically feasible. Substantial data gaps have been identified, and the primary purpose of this ANPR is to obtain some of this missing information. After OSHA has collected information needed to determine what constitutes a necessary and feasible exposure limit, the Agency will publish a Notice of Proposed Rulemaking requesting comments on a revised standard for occupational exposure to formaldehyde.

4. Health Effects

There is a substantial volume of scientific information regarding the possible hazards of occupational exposure to formaldehyde. OSHA is reviewing this information to determine (1) the extent of the health hazards that exist at the present permissible exposure limits of 3 ppm (TWA), 5 ppm (ceiling), and 10 ppm (peak); (2) the extent to which current conditions of occupational exposure of formaldehyde pose health risks, and (3) the availability of effective measures to reduce any existing risk.

The ability of formaldehyde to cause reversible sensory irritation of the eyes, nose, and throat at levels permitted by the present standard has been well documented.

Based on a review of the available epidemiologic studies and the Consensus Panel's report, OSHA concludes that the evidence presently available from human studies alone is inadequate to make any determination with regard to formaldehyde's potential carcinogenicity. Several studies presently available, although suggestive of an effect, do not provide conclusive evidence of a causal relationship between formaldehyde exposure and cancer. For example, excess deaths from brain cancer and leukemia have been reported in professional groups including morticians, anatomists, and pathologists [Exs. 42-81, 42-113, 42-124]. Levine estimates that, overall, the increased incidence is approximately 2-fold [Ex. 64]. Similar findings have not been reported in groups which were exposed only to formaldehyde gas instead of formalin. Several commenters have hypothesized alternative explanations for these results [Exs. 44-3, 45-1, 69-19b; Tr. 243-246, 621-626], including social class bias, changes in diagnostic techniques over recent years, and slow-growing viruses. The Epidemiology Panel of the Consensus

Workshop examined and rejected detection bias for the excess brain cancer among anatomists, but they also concluded that "the association between professional groups engaged in preservation of human tissues and brain cancer does not necessarily implicate formaldehyde" [Ex. 70-56, p. 338]. OSHA has not yet determined how the data on professional groups should influence its decisions regarding regulation of formaldehyde.

5. Production and Use

Formaldehyde (CH_2O) is the simplest member of the aldehyde class of chemicals. Pure monomeric formaldehyde is a colorless, pungent gas at ordinary temperatures. Aqueous formaldehyde, or formalin, is a clear, colorless solution which is about 37% dissolved formaldehyde by weight and generally contains 10-15% methanol added to prevent polymerization [Ex. 42-41].

Formaldehyde is produced commercially from the catalytic oxidation of methanol, using either silver oxide or mixed metal oxide as the catalyst [Ex. 70-1]. Formaldehyde is a major industrial chemical, having the 28th highest production volume in the United States. In 1983, about 5.4 billion pounds of formaldehyde (as a 37% aqueous solution) were manufactured [Ex. 42-127].

Formaldehyde is primarily used as an intermediate in the manufacture of a variety of derivatives, with about 53% of production consumed in the manufacture of thermosetting resins including phenol-formaldehyde resins, urea-formaldehyde resins, and melamine-formaldehyde resins [Ex. 8]. An additional 7% is consumed in the production of thermoplastic acetal resins. About 35% is used in synthesis of high volume chemicals including pentaerythritol, hexamethylenetetramine, and butanediol. Two percent is used in textile treating. Small amounts of formaldehyde are present as preservatives or bactericides in consumer products such as cosmetics, shampoos, and glues. The general population and workers in downstream industries can also be exposed to formaldehyde through offgassing from: (1) urea-formaldehyde foam insulation; (2) formaldehyde resins used in wood products such as kitchen cabinets, particleboard, and hardwood plywood; and (3) textile resins used for the permanent press process.

The EPA [Exs. 14, 42-41, 70-2] has defined three categories of exposure to formaldehyde based on nonconsumptive use, pseudoconsumptive use, and

consumptive use. In nonconsumptive use, chemical identity does not change. Examples of such uses are disinfectants and preservatives including embalming fluid. In pseudoconsumptive use, chemical identity changes, but not irreversibly. In pseudoconsumptive use, formaldehyde can be regenerated and released during numerous downstream uses, which leads to potential exposure for large numbers of workers and consumers. Three pseudoconsumptive uses are production of urea formaldehyde resins and concentrates and production of hexamethylenetetramine. Consumptive use results in irreversible change of chemical identity. Examples include manufacture of phenol-formaldehyde and melamine-formaldehyde resins, acetyl resins, pentaerythritol, trimethylolpropane, and butanediol. In consumptive use, formaldehyde serves as a feedstock for preparation of other chemicals. Thus, exposure potential is limited to manufacture of the product with little, if any, formaldehyde release expected from the product under normal conditions of use.

6. Potential for Occupational Exposure

OSHA has four estimates of the total number of workers potentially exposed to formaldehyde. Based on a 1972-1974 survey of 5,000 industries, NIOSH estimated that 1.6 million workers are potentially exposed to formaldehyde [Ex. 42-86]. In 1979, the study conducted by Booz, Allen, Hamilton, Inc. for the Formaldehyde Subgroup of the Synthetic Organic Chemical Manufacturers Association (The SOCMA study) [Ex. 8] estimated that 1.4 million workers are exposed to formaldehyde in 57,000 plants. Based on the SOCMA report and projections from OSHA inspection data, the Center for Policy Alternatives (CPA) estimated in 1981 that 1.34 million workers are potentially exposed to formaldehyde [Ex. 70-1]. About 850,000 exposures were believed to be below 0.25 ppm, 243,000 between 0.25 and 0.49 ppm, 117,000 between 0.5 and 0.99 ppm, 82,000 between 1.0 and 1.9 ppm, and 52,000 at or above 2 ppm. According to the authors, estimates for some exposure categories were much more accurate than for others. In a 1982 study [Ex. 16], Clement Associates estimated that about 1.3 million persons are potentially exposed to formaldehyde, based on review of NIOSH and OSHA inspections, a 1981 EPA study, and the SOCMA report. Based on information in the Clement study, the ORA report estimated that 3% of the workers were exposed at levels above 2 ppm. It was estimated that another 8% were exposed at concentrations between 1 and 2 ppm,

that 77% were exposed to levels between 0.5 and 1 ppm, and that 12% were exposed to levels below 0.5 ppm [Ex. 43].

Information on workers exposure to formaldehyde in selected industries is available from EPA [Ex. 42-41]. This information has been updated from earlier reports [Exs. 14, 70-2], received public scrutiny in 1983, and is the most recent exposure assessment available. However, it does not include all of the industries examined by Clement and CPA and cannot be used to provide an estimate of overall potential exposure. There are indications from review of information in the EPA study that, for certain industries, exposure levels reported in studies that are several years old may no longer be relevant to present conditions since the data do not reflect recent industry attempts to reduce formaldehyde levels.

Although the studies available to OSHA indicate consistency in determining the overall number of persons exposed to formaldehyde, they show considerable divergence on estimates of levels of exposure that occur. This divergence occurs even though the reports interlock and build upon each other, with subsequent studies relying on the SOCMA report. For example, the CPA study estimated that 90% of the exposures are below 1 ppm, which agrees with the ORA estimate of 89%. However, ORA estimated that only 12% are below 0.5 ppm and CPA estimated 80% are below 0.5 ppm. In order to better determine the consequences of various regulatory options, OSHA seeks to obtain information that accurately reflects prevailing conditions as they now exist in the formaldehyde industry along with information about new uses or shifts in usage patterns that would indicate a decrease or increase in hazard potential. OSHA solicits all public comment that would assist in determining present levels of occupational exposure to formaldehyde.

The ORA Report selected apparel industry workers, funeral service employees, foundry workers, resin manufacture employees, pathologists, and wood furniture manufacture workers as groups at potentially high risk from exposure to formaldehyde, either because of high exposure concentrations or widespread exposure potential [Ex. 43]. The ORA Report also identified the following groups as having either a large number of persons exposed or a potential for exposure to high levels of formaldehyde: Formaldehyde production workers, plywood and particleboard manufacture

workers, plastics manufacture workers, high school and university instructors, and hospital laboratory technicians and assistants. Other groups known to be exposed to formaldehyde include workers in photographic processing, industrial and specialty chemical manufacture, textile manufacture, paper and paperboard manufacture, abrasive products manufacture, mobile home manufacture, and building construction [Exs. 8, 70-1]. OSHA seeks information on the nature of employee exposure in these industries and in any other industry where formaldehyde exposure occurs. OSHA is particularly interested in how this exposure occurs, what levels are involved, whether exposure is full-time or part-time, whether exposure is solely to formaldehyde gas, formalin, or to other forms of formaldehyde, and what percentage of the overall workforce is exposed to formaldehyde.

7. Control Options

Many uses have been found for formaldehyde due to its status as a highly reactive and relatively low cost chemical. Exposure to formaldehyde occurs in many sectors of U.S. industry. Not only do the types of exposure differ (e.g., part-time vs. full-time, liquid vs. gas), but the processes used are diverse and the problems of each industry sector are often unique. Given this situation, control measures which are considered technologically and economically feasible for one sector of industry may be irrelevant to another sector. Even though the problems in various industries with potential for employee exposure to formaldehyde may differ greatly, a standard for formaldehyde must ensure the protection of the health of all workers exposed to formaldehyde.

Information available to OSHA indicates that control measures in some sectors of the formaldehyde industry are not unique. Primary formaldehyde producers and other large scale chemical synthesis operations using formaldehyde appear to be typical of large scale continuous operations that rely on modifications of process equipment [Ex. 8] and leak tightening [Ex. 70-1] to reduce exposure. Other industry sectors, such as resin manufacture and production of specialty chemicals, appear to be typical batch operations, relying primarily on local ventilation to control exposure [Exs. 8, 70-1].

There is substantial evidence available to OSHA which indicates that some industries have achieved considerable success in lowering formaldehyde emissions from their products through non-traditional methods. For example, over 95% of the

hardwood plywood manufactured in the U.S. uses urea-formaldehyde resins [Exs. 69-7, 70-5]. The industry has substantially lowered formaldehyde emissions from its products by reformulating resins to contain less formaldehyde and by coating or laminating wood surfaces to provide a barrier to prevent formaldehyde's escape [Exs. 69-7, 70-5, 70-15]. Some companies have explored the use of scavenging solutions to reduce the amount of formaldehyde in the final product [Ex. 70-5]. However, this industry has been unable to substitute phenol-formaldehyde resins, as used in softwood plywood, for urea-formaldehyde resins because an undesirable color is often imparted to the wood [Ex. 70-5]. Changes in hardwood plywood industry products have occurred as the result of demands from downstream users, but these changes have also benefitted employees in the upstream industry [Ex. 69-7]. The particleboard industry has also used new resin formulations, board finishes, and scavengers to substantially reduce the formaldehyde emissions from their products [Exs. 69-9, 70-8, 70-9, 70-16]. It appears that the particleboard industry may be able to use phenol-formaldehyde resins and isocyanate resins as product substitutes, but such substitutes would increase production costs [Exs. 70-8, 70-9, 70-16].

Resins containing formaldehyde have been used for about the last 25 years to impart permanent press characteristics and crease and shrink resistance to a wide variety of fabrics, primarily cellulose (cotton, rayon, linen) and cellulose/polyester blends [Exs. 8, 70-14]. An estimated 60-85% of all apparel fabrics, or approximately 7 billion yards of textiles produced in the U.S., are finished with formaldehyde resins [Ex. 69-13]. Formaldehyde resins are applied at a late stage in textile manufacture. This tends to limit the number of workers exposed in the industry [Ex. 69-13]. However, these processes use steam heat and can be very difficult to control [Ex. 8]. Textile manufacturers have relied primarily on process modification and resin reformulation to reduce employee exposure to formaldehyde. The wash-and-wear technology of the 1950s, when formaldehyde released from textiles was in the range of 2,000 to 4,000 micrograms per gram ($\mu\text{g/g}$) of fabric, was replaced by the permanent press process in the mid-1960s. Information collected by the American Textile Manufacturers Institute (ATMI) [Ex. 70-14] shows that further advances in resin formulation have continued to reduce formaldehyde levels from an average of

534 $\mu\text{g/g}$ in 1975 to 345 $\mu\text{g/g}$ in 1983. ATMI expects that the new low-formaldehyde resins will gain wider usage, even though a lower quality permanent press finish is produced.

The apparel manufacturing industry employs the largest group of workers potentially exposed to formaldehyde. The most recent estimate is 777,000 persons [Ex. 42-41]. This industry has a number of unique characteristics. Among apparel workers, 81% are women and 27% are members of minority groups. Competition from foreign countries with low-cost labor is strong. In fact, according to the American Apparel Manufacturers Association (AAMA), imports from foreign sources currently account for 25% of the U.S. apparel market [Ex. 69-25d]. Many plants would be considered small businesses, and they tend to rent both space and equipment. According to ATMI, in 1981, rental expenses constituted 57% of this industry's expenditures on capital outlays compared to 13% for all industry. The apparel manufacturing industry also spent an average of \$500 per employee for capital items compared to a textile industry average of \$4,000 per employee [Ex. 70-14]. About 80% of the workers in an apparel plant are sewing machine operators [Ex. 69-25d].

Because of the nature of apparel manufacturing work, the reduction of in-plant exposure would probably require general dilution ventilation in most cases. The cost for installing general ventilation equipment to achieve as 1 ppm, 30 minute ceiling was estimated by the SOCMA report to be \$265 per employee for firms with 20 or fewer employees and \$150 per employee for those with over 500 employees [Ex. 8]. The possible cost disadvantage to smaller firms may be underestimated, however, since, as pointed out by ATMI, companies in a landlord-tenant relationship may have special problems in performing the building modifications required to install ventilation [Ex. 70-14].

8. Cost Estimates for Control of Formaldehyde

There are three studies available to OSHA which examine the potential costs of controlling exposure to formaldehyde. Two of these, the SOCMA report of 1979 [Ex. 8] and the CPA study of 1981 [Ex. 70-1] examine the overall industry. However, they have limited usefulness because they address only a ceiling exposure and their estimates are based on exposure levels that appear to have been lowered voluntarily by industry. Some cost

estimates, in retrospect, were probably also too high since they were based on conventional engineering controls. For example, the trend in industries that use resins has been to reduce formaldehyde levels in their products by reformulating the resins to decrease the amount of excess formaldehyde, a relatively inexpensive method as compared to conventional control technology [Ex. 42-41]. A third study conducted by A.D. Little [Ex. 50] for the Formaldehyde Institute contains recent figures for two industries, apparel manufacture and manufactured housing. The report evaluated different exposure conditions applicable to EPA's authority under TSCA, and does not address control to various permissible exposure limits, such as would be considered by OSHA. The SOCMA study stated that it would cost less to implement controls which would achieve a 1 ppm TWA than it would to achieve a 1 ppm ceiling, but it did not address this alternative in depth.

Given these limitations, information available from the SOCMA study indicates an estimated capital cost of \$840 million with an annual cost of \$327 million to control the exposures of 1.4 million employees to 1 ppm or below, as a 30-minute ceiling. The CPA study provides a "most likely estimate" of capital costs for a 1 ppm ceiling of \$458 million annual operating costs of \$171 million. CPA estimated that these costs would be \$373 million in capital costs and \$140 million in annual operating costs for a 2 ppm ceiling compared to \$690 million in capital costs and \$254 million in annual operating costs to achieve a 0.5 ppm ceiling. The costs of other provisions such as medical surveillance and exposure monitoring are not included in any of the above figures. The A.D. Little study estimated an investment of \$399 million and operating costs of \$95.6 million to achieve a 33% reduction in formaldehyde levels in the apparel industry through installation of general ventilation. It also predicted that a number of plants would close, resulting in the loss of 135,000 jobs in apparel manufacture. There would also be upstream consequences in industries such as textile manufacturing and cotton growing. Using EPA's estimate that occupational exposure in the apparel industry averaged 0.64 ppm, a 33% reduction would reduce levels to below 0.5 ppm as a TWA.

Request for Comments

OSHA solicits information and comments relevant to the reduction of formaldehyde exposure. The public is invited to express opinions as to what provisions, including but not limited to

those which set the permissible exposure limit(s), should be included in the revised formaldehyde standards that will be published by OSHA. OSHA is especially interested in methods, costs, and effectiveness of control strategies that have already been employed to reduce exposure to formaldehyde. The questions below will provide specific guidance on OSHA's request for information.

A number of submissions concerning the health effects of formaldehyde and concomitant risks have been received by OSHA in response to the recent request for information and public meeting. While the public is invited to submit any relevant information regarding regulation of formaldehyde, information submitted in the past need not be resubmitted for consideration in the upcoming rulemaking.

Permissible Exposure Limit

In order to provide adequate protection of employee health, should a standard for formaldehyde contain an 8-hour time-weighted average (TWA), a short-term exposure limit (STEL), or some combination of both exposure limits? What should these exposure limits be? What methods of sampling and analysis are available to measure exposure at these levels? Please provide the rationale for your answers.

Both the Celanese Chemical Corporation and the E.I. Du Pont de Nemours Company indicated at the public meeting that they have established corporate standards of 1 ppm as an 8-hour TWA with a STEL of 2 ppm for formaldehyde [Tr. 27, Tr. 640]. Which other companies have internal standards for formaldehyde? What are the standards? What are the bases for such standards?

Action Level

In certain occupational health standards, some provisions apply only when an action level, often set at one-half of the permissible exposure limit, is exceeded. When health risks are low, action levels are appropriate because they can reduce or eliminate regulatory burdens. OSHA requests comments and information on the following:

(a) Is an action level appropriate for some or all segments of the formaldehyde industry? What impact would an action level have on employee health?

(b) What are appropriate action levels in the various industry segments? Which regulatory provisions should be modified or eliminated when exposures are under the action level?

(c) What would be the cost savings expected to result from incorporation of an action level provision?

Methods of Compliance

For OSHA to promulgate a revised standard for formaldehyde, all provisions of the standard must be economically and technologically feasible. Consideration of this issue most often focuses on the availability of engineering and work practice controls and personal protection to limit employee exposure to toxic substances or materials. In the case of formaldehyde, OSHA will also consider other approaches, such as product substitution.

In describing the technologies available to achieve control of exposure to formaldehyde, please discuss in detail how these controls are used, how long it would take to implement controls not currently in use, the costs of controls, and the levels of airborne formaldehyde that can be achieved through their use. OSHA is particularly interested in the following information:

(a) Under what circumstances are engineering controls (including local and general ventilation), substitution of products or processes with materials not containing formaldehyde, modification of processes to use materials containing less formaldehyde, or modification of equipment (e.g., booths, islands, cabs), useful for limiting worker exposure to formaldehyde?

(b) Under what circumstances would work practices, housekeeping, or administrative controls, such as worker rotation, be useful for limiting employee exposure to formaldehyde?

(c) Are there conditions in any sector of industry which would make it unreasonable to use engineering controls and work practices to reduce exposure to formaldehyde?

(d) In what operations should personal protective equipment, including respirators, be required?

(e) Have there been technological advances or changes aimed at improving productivity, product quality, or consumer exposure to formaldehyde which have also resulted in reductions in formaldehyde exposures at the worksite?

(f) What are the availability, price, and serviceability of substitutes for products containing formaldehyde?

(g) How have regulatory activities of state agencies and other Federal agencies affected worker exposure to formaldehyde?

Exposure Monitoring

Do employers presently monitor employee exposure to formaldehyde? What factors are used to determine monitoring frequency and the employees whose exposure is to be measured? What sampling and analytical methodologies are used for exposure monitoring?

Medical Examinations

Do employers provide medical examinations for formaldehyde-exposed workers? What procedures are appropriate for monitoring the health of formaldehyde-exposed workers? What formaldehyde-related illnesses have been observed? How prevalent are such illnesses? Have any employees transferred away from or left a given job because they were unable to tolerate their exposure to formaldehyde?

Employee Training

How are employees currently informed of the hazards associated with formaldehyde? What types of training programs are appropriate for formaldehyde-exposed employees?

Economic Data

OSHA's rulemaking will comply with Executive Order 12291, which requires the preparation of a regulatory impact analysis of all major actions; and with the Regulatory Flexibility Act, which requires the preparation of regulatory flexibility analyses for actions having a significant economic impact on a substantial number of small entities. To this end, OSHA is soliciting information on the financial condition of the affected industries to calculate the economic implications of compliance with the present formaldehyde standard as compared with anticipated modifications of this standard. OSHA requests comments and information on the following:

(a) For each industry potentially affected by a new formaldehyde standard, what are the major production processes in which workers are exposed to formaldehyde? What are the sources of exposure? How many workers are exposed? What are the concentrations, the durations, and the frequencies of such exposures?

(b) What costs have been incurred by industry to implement controls introduced for the purpose of lowering employee exposure to formaldehyde? How effective have these controls been in reducing formaldehyde exposures? Have these controls affected productivity? Have any of these measures helped to reduce workplace

hazards in downstream industries using products containing formaldehyde?

(c) What were the total annual volume and dollar value of formaldehyde product output, shipments, and inventories for at least the last 5 years?

(d) What was the total annual investment, appropriately categorized as either replacement, expansion, modernization, or environmental health and safety related expenditures for at least the last 5 years?

(e) What were the retained earnings, after tax income, total assets, stockholders' equity, net worth, debt equity ratios, and depreciation charges for at least the last 5 years.

(f) What were the rates of return on assets, equity, or net worth for at least the last 5 years.

(g) What is the degree of market concentration in the industry? (Please give special attention to the role of small businesses and approximate numbers of firms in the industry each year.)

(h) What is the geographic dispersion of the industry and its customers?

(i) What were the annual volume and dollar value of imports and exports for at least the last 5 years? How would this be affected by a more stringent U.S. occupational health standard for formaldehyde?

(j) What were the total annual employment and labor turnover for the industry for at least the last 5 years?

(k) Can you identify any unique characteristics of your industry (e.g., rental of capital equipment, unique employee skills) that could affect your ability to achieve compliance with a formaldehyde standard?

Environmental Effects

The National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321, *et seq.*), the Council on Environmental Quality (CEQ) regulations (40 CFR Part 1500; 43 FR 55978, November 29, 1978), and the Department of Labor (DOL) NEPA Compliance Regulations (29 CFR Part II; 45 FR 51187 *et seq.*, August 1, 1980) require that Federal agencies give appropriate consideration to environmental issues and impacts of proposed actions significantly affecting the quality of the human environment. OSHA is currently collecting written information and data on possible environmental impacts that may occur outside of the workplace as a direct or indirect result of promulgation of a revised standard for occupational exposure to formaldehyde. Such information should include any negative or positive environmental effects that could be expected to result from a revised regulation.

OSHA requests comments and information on the following:

(a) How would alternative regulations of worker exposure to formaldehyde alter ambient air quality, water quality, solid waste disposal, or land use?

(b) How would product substitutions, performed to comply with a formaldehyde regulation, affect the general public's exposure to formaldehyde?

Public Participation

Interested persons are invited to submit comments on these and other pertinent issues relating to the development of a revised standard for occupational exposure to formaldehyde by August 15, 1985. Comments should be sent in quadruplicate to the Docket Officer, at the address noted above where they will be available for inspection and copying. The data received will be carefully reviewed by OSHA for use in preparation of a Notice of Proposed Rulemaking for formaldehyde.

This Advance Notice of Proposed Rulemaking was prepared under the direction of Robert A. Rowland, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue, NW., Washington, D.C. 20210. It is issued pursuant to section 6(b) of the Occupational Safety and Health Act (84 Stat. 1593; 29 U.S.C. 655).

List of Subjects in 29 CFR Part 1910

Occupational safety and health.

Signed at Washington, D.C. this 9th day of April 1985

Robert A. Rowland,

Assistant Secretary of Labor.

[FR Doc. 85-8868 Filed 4-15-85; 8:45 am]

BILLING CODE 4510-10-26-M

VETERANS ADMINISTRATION

38 CFR Part 19

Appeals—General; Rules of Practice

AGENCY: Veterans Administration.

ACTION: Proposed regulations.

SUMMARY: As a result of recent changes in legislation, the Veterans Administration is amending the Appeals Regulations of the Board of Veterans Appeals to reflect the expansion of the Board's jurisdiction to include questions concerning certain benefits for surviving spouses and children of deceased veterans. The Board of Veterans Appeals Rules of Practice are also being revised to provide for: informal hearings

requests for opinions from the General Counsel of the Veterans Administration in individual appeals; reconsideration involving allegations of the use of false or fraudulent evidence to obtain benefits from the Board; and vacating decisions.

DATE: Comments must be received by May 17, 1985.

ADDRESSES: Interested persons are invited to submit written comments, suggestions, or objections regarding the proposal to the Administrator of Veterans Affairs (271A), Veterans Administration, 810 Vermont Avenue, NW, Washington, DC 20420. All written comments received will be available for public inspection in the Veterans Services Unit, room 132, at the above address only between the hours of 8:00 a.m. and 4:30 p.m. Monday through Friday (except holidays) until June 3, 1985.

FOR FURTHER INFORMATION CONTACT:

Mr. Jan Donsbach, phone (202) 389-2978.

SUPPLEMENTARY INFORMATION: Pub. L. 97-377 replaced certain benefits to surviving spouses and children of members of the Armed Forces who died on active duty before August 13, 1981, and former members who died as a result of service-connected disability incurred or aggravated before August 13, 1981. These benefits are intended to replace certain Social Security benefits withdrawn by Pub. L. 97-35, (The Omnibus Budget Reconciliation Act of 1981). Pursuant to Pub. L. 97-377, section 156, by Executive Order 12436 of July 29, 1983, the President designated the Veterans Administration as the Agency responsible for administering these benefits. The Veteran's Administration is amending section 19.2(b), the regulation listing examples of the subject matter of appeals to the Board of Veterans Appeals, to reflect the Board's expanded jurisdiction to cover questions involving these benefits.

The proposed amendments to §§ 19.157 and 19.176 are intended to formalize, respectively, the traditional practices with respect to informal hearings by the authorized representatives of appellants and the procurement of opinions of the General Counsel on legal questions in individual appeals.

The proposed amendment to § 19.179 is designated to afford appellants notice when opinions of the General Counsel are obtained under amended § 19.176, as is now done in the case of advisory medical opinions.

The proposed amendments to §§ 19.180, 19.185, 19.186 and 19.187 and the new § 19.201(c) are designed to provide a formal procedure for reconsidering decisions based upon the

allegation that an allowance of benefits by the Board has been materially influenced by false or fraudulent evidence submitted by or on behalf of the appellant. This procedure is designed to ensure an equitable uniformity in the limited number of cases involved, which are now handled individually under § 19.101(b).

The new § 19.201 is designed to formalize traditional practice in vacating decisions.

The Administrator has certified that these regulations will not, if promulgated, have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (RFA), 5 U.S.C. 601-612. Pursuant to 5 U.S.C. 605(b), this regulation therefore is exempt from the initial and final regulatory flexibility analyses requirements of sections 603 and 604. The reason for this certification is that the impact of these regulations is only upon individual benefit claimants. It will have no significant direct impact on small entities (i.e., small businesses, small private and nonprofit organizations, and small governmental jurisdictions).

The Agency has also determined that these regulations are nonmajor in accordance with Executive Order 12291, Federal Regulation, inasmuch as they will only effect individual claimants seeking Veterans Administration benefits, they will not result in any significant effect on the economy, they will not have any significant impact upon private or governmental costs, and they will not effect business enterprises or otherwise have any adverse effect on the economy.

There is no Catalog of Federal Domestic Assistance number involved.

List of subjects in 38 CFR Part 19

Administrative practice and procedure, Claims Veterans.

By direction of the Administrator.

Approved: April 9, 1985.

Everett Alvarez, Jr.,
Deputy Administrator.

PART 19—BOARD OF VETERANS APPEALS

38 CFR Part 19 Board of Veterans Appeals is amended as follows:

1. Section 19.2 is amended by adding an additional subject to the end of the listing contained in that section, to read as follows:

§ 19.2 Subject matter of appeals.

Benefits for surviving spouses and children of deceased veterans under Pub. L. 97-377, section 156. (38 CFR 3.812(d))

2. Section 19.157 is amended by adding a new paragraph (d) to read as follows:

§ 19.157 Rule 57; General.

(d) *Informal hearings.* This term is used to describe situations in which the appellant cannot, or does not wish to, appear. In the absence of the appellant, the authorized representative in Washington, DC, may present oral arguments to the Board without personally appearing before the Board of Veterans Appeals hearing panel. These arguments will be recorded and transcribed by Board personnel for subsequent review by the panel members. This procedure will not be construed to satisfy an appellant's request to appear in person. (38 U.S.C. 4002)

3. Section 19.176 is amended by revising the title and by adding a new paragraph (c) to read as follows:

§ 19.176 Rule 76; Medical opinions and opinions of the General Counsel.

(c) *Opinion of the General Counsel.* The Board may obtain an opinion from the General Counsel of the Veterans Administration on legal questions involved in the consideration of an appeal. (38 U.S.C. 4004(c))

§ 19.179 [Amended]

4. Section 19.179 is amended by removing the word "medical" from the title.

5. In § 19.180, paragraph (b) is revised to read as follows:

§ 19.180 Rule 80; The decision.

(b) *Disposition of issues.* (1) The decision of the Board will dispose of each issue on appeal by allowance, denial, remand or dismissal, in whole or in part; or (38 U.S.C. 4004(a))

(2) If on reconsideration it is determined that an allowance of benefits by the Board has been materially influenced by false or fraudulent evidence submitted by or on behalf of the appellant, the prior decision of the Board will be vacated and the appeal voided with respect to those benefits.

6. In § 19.185, paragraph (b) is revised and a new paragraph (c) is added to read as follows:

§ 19.185 Rule 185; When reconsideration is accorded.

(b) Upon discovery of new and material evidence in the form of records or reports of the military, naval or air service department concerned or officially correctly service department record; or (38 U.S.C. 4003, 4004(b))

(c) Upon allegation that an allowance of benefits by the Board has been materially influenced by false or fraudulent evidence submitted by or on behalf of the appellant.

7. In § 19.186, paragraph (b)(1) is revised to read as follows:

§ 19.186 Rule 86; Filing and disposition of a motion for reconsideration.

(b) *Disposition.* * * *

(1) *Motion denied.* The appellant and representative or other appropriate party will be notified if the motion is denied. The notification will be signed by the Chairman and will include reasons why the allegations are found insufficient. This constitutes final disposition of the motion.

8. Section 19.187 and the cross-reference following it are revised to read as follows:

§ 19.187 Rule 87; Evidence considered.

(a) *Reconsideration based upon an allegation of obvious error of fact or law or new and material service department records or reports.* Reconsideration of an appellate decision for error shall be limited to review of the evidence of record at the time the decision was entered, but the Board may secure additional medical or legal opinion. Additional evidence, apart from service department records, submitted following the decision being reconsidered is subject to the provisions of Rule 94 (§ 19.194) concerning new and material evidence. (38 U.S.C. 4003, 4009)

(b) *Reconsideration based upon an allegation of false or fraudulent evidence.* Reconsideration of an appellate decision based upon the allegation that an allowance of benefits by the board has been materially influenced by false or fraudulent evidence submitted by or on behalf of the appellant will be limited to a review of the evidence of record at the time the decision was entered and only such additional evidence as it is required, in the Board's judgement, to establish the veracity of the evidence in question. The reconsideration panel will not readjudicate the underlying issue(s).

Cross Reference: When reconsideration is accorded. See Rule 85, § 19.185. Disposition of

issues. See Rule 80, § 19.180. Vacating a decision. See Rule 101, § 19.201.

9. The center heading "MISCELLANEOUS" is added directly preceding § 19.200.

10. New § 19.201 is added to read as follows:

§ 19.201 Rule 101; Vacating a decision.

An appellate decision may be vacated by the Board of Veterans Appeals at any time upon request of the appellant or his/her representative or on the Board's own motion:

(a) *Due process.* Where there has been a prejudicial failure to afford the veteran the due process of law. Where there has been a failure to honor a request for a hearing, and a hearing is subsequently scheduled but the appellant fails to appear, the decision will not be vacated.

(b) *False or fraudulent evidence.* Where it is determined that an allowance of benefits by the Board has been materially influenced by false or fraudulent evidence submitted by or on behalf of the appellant, the prior decision will be vacated only with respect to the issued or issues to which, within the judgment of the Board, the false or fraudulent evidence was material.

Cross Reference: The decision. See Rule 80; § 19.180. When reconsideration is accorded. See Rule 85; § 19.185.

(38 U.S.C. 210(c)(1); Pub. L. 97-377, Sec. 156) [FR Doc. 85-9212 Filed 4-16-85; 8:45 am]

BILLING CODE 8320-01-M

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 62**

[A-4-FRL-2819-6]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants; South Carolina: Revision in 111(d) Plan for TRS From Existing Kraft Pulp Mills; Negative Declaration for Primary Aluminum Plants

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve a source-specific revision in South Carolina's 111(d) plan for total reduced sulfur (TRS) emissions from existing kraft pulp mills. On December 13, 1984, the State submitted a revised emission standard and an extended compliance schedule for two emission points at Stone Container Corporation's facility in Florence which are presently exceeding

TRS emission standards. This submittal included economic and technical information justifying the new limit and compliance schedule. The approval of this 111(d) plan revision is consistent with EPA policy on welfare-related pollutants.

In addition, on May 3, 1983, South Carolina certified that there were no primary aluminum plants in the state which were subject to the requirements of section 111(d) of the Clean Air Act. EPA proposes to approve South Carolina's negative declaration for existing primary aluminum plants.

DATES: To be considered, comments must be received on or before May 17, 1985.

ADDRESSES: Written comments should be addressed to Janet Hayward of EPA Region IV's Air Management Branch (see Region IV address below). Copies of the State's submittal are available for review during normal business hours at the following locations:

Environmental Protection Agency,
Region IV Office, Air Management
Branch, 345 Courtland Street, N.E.,
Atlanta, Georgia 30365

South Carolina Department of Health
and Environmental Control, 2600 Bull
Street, Columbia, South Carolina
29201

FOR FURTHER INFORMATION CONTACT: Janet Hayward of the EPA Region IV Air Management Branch, at the above address and following phone: 404/881-3966, or FTS 257-3966.

SUPPLEMENTARY INFORMATION: On February 12, 1980, the South Carolina Board adopted regulations for existing kraft pulp mills. At that time, Stone Container Corporation began to develop a strategy to bring their Florence mill into compliance with the new regulation emission standards. Since 1980, Stone Container has worked with the State and EPA towards achieving TRS compliance in a cost-effective manner. On February 8, 1984, the South Carolina Department of Health and Environmental Control (SCDHEC) submitted a 111(d) plan revision for Stone Container which included alternate emission limits for the digesters and an extended compliance schedule for the evaporator hot-well vents. Complete documentation justifying the State's proposed plan revision was lacking in the February 8, 1984, submittal. Therefore, EPA requested that more comprehensive cost information be submitted. On December 13, 1984, South Carolina sent EPA a complete submittal containing adequate justification for the revised digester

emission limit and extended evaporator compliance schedule.

Under South Carolina Regulation 62.5, Standard No. 4, Section VIII, Part B, the digester system at Stone Container's mill is subject to a TRS emission standard of 5 ppm (.02 lb TRS per ton of air-dried pulp). The State intends to relax this limit to 1847 ppm, or .29 lb TRS per ton of air-dried pulp (TADP). This is the current actual emission level resulting from the digester blow gases. This equates to a change in allowable TRS emissions of approximately 66 tons per year, or about 16 pounds per hour.

The evaporator hot-well vents at the Stone Container facility are presently emitting .39 lb TRS/TADP, which is above their regulation emission limit of .02 lb TRS/TADP (5 ppm). The company plans to construct a TRS incineration system which would bring the evaporator system into compliance with regulation standards. Final compliance will be required forty-nine weeks after EPA approval of this plan revision.

South Carolina's Regulation 62.5, Standard No. 4, Section VIII, Part C, provides for case-by-case exceptions to the regulatory TRS emission limits in Section VIII, Part B, " * * * if the owner or operator of a source of total reduced sulfur compounds * * * can demonstrate that compliance with applicable portions of Part B would not be economically feasible." The regulation requires that all pertinent cost information be submitted with the source's request for alternate emission limits and that the request be submitted to EPA for approval as a revision to the South Carolina 111(d) plan for TRS. Under Regulation 62.5, Standard No. 4, Section VIII, Part G, sources may request alternate compliance schedules if adherence to the existing schedule is not technically feasible.

Except for the evaporators and digesters, all significant emission points at Stone Container's Florence mill are being controlled to guideline levels. Stone Container Corporation has documented that the digesters are already emitting low levels of TRS (20 percent of the typical uncontrolled levels) and that the estimated costs to control the digesters at their Florence mill would be \$2.48 per ton of air dried pulp. The Company has agreed to control TRS emissions from the evaporator hot-well vents by incinerating the noncondensable gases in an existing power boiler. They have also requested a new compliance schedule which will bring the evaporators, and thus the entire mill, into compliance with regulatory TRS

standards forty-nine weeks after the plan revision is approved by EPA.

Stone Containers has modeled the total TRS emissions from their mill to determine the air quality impact of this plan revision. Modeled concentrations at selected population points three to ten miles from the mill were below detectable threshold levels. The company has also substantiated their request for an alternate digester emission limit by such factors as rural mill location and lack of public complaints. This information was submitted to EPA on December 13, 1984 with the State's final request for EPA approval of the TRS plan revision.

EPA has reviewed this documentation and has found that the State's request is adequately justified by economic, technical, and other related criteria. EPA therefore proposes to approve the emission limit relaxation and extended compliance schedule as submitted by South Carolina for Stone Container Corporation.

Further details pertaining to this source-specific plan revision are contained in the technical support document, which is available for public inspection at EPA's Regional Office in Atlanta, Georgia.

In addition, South Carolina is required to submit a 111(d) plan for the control of fluoride emissions from existing primary aluminum plants. If there is no facility of this type in the State, the State is to submit a letter to that effect (negative declaration). The absence of such plants in the State was certified by a letter from John E. Jenkins, P.E., Deputy Commissioner for Environmental Quality Control, to Mr. Charles R. Jeter, Regional Administrator, on May 3, 1983. Today, EPA also proposed to approve South Carolina's negative declaration for primary aluminum plants.

All interested persons are invited to submit written comments on the proposed actions. After reviewing all comments submitted, the Administrator of USEPA will publish the Agency's final action in the Federal Register.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Under 5 U.S.C. 605(b), the Administrator has certified that 111(d) approvals do not have a significant economic impact on a substantial number of small entities. (See 46 FR 8709.)

List of Subjects in 40 CFR Part 62

Air pollution control, Fluoride, Sulfur, Administrative practice and procedure, Intergovernmental relations, Reporting and recordkeeping requirements.

(Sec. 111(d) of the Clean Air Act (42 U.S.C. 7411(d)))

Dated: March 22, 1985.

Charles R. Jeter,
Regional Administrator.

[FR Doc. 85-9202 Filed 4-16-85; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 81

[Docket No. AM107-VA-6; A-3-FRL-2819-7]

Proposed Approval of Redesignation of Attainment Status for the Commonwealth of Virginia With Respect to Carbon Monoxide

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: This notice announces EPA's proposed approval of air quality designation change for Fairfax County in Virginia, from "Does not meet primary standards" to "Cannot be classified or better than national standards", for the primary and secondary National Ambient Air Quality Standards (NAAQS) for carbon monoxide (CO). This proposed revision is based on eight consecutive calendar quarters of air quality data submitted by Virginia demonstrating attainment. EPA proposes approval of this redesignation request as it meets the necessary requirements of section 107 of the Clean Air Act and current EPA policy.

DATE: Comments must be submitted on or before May 17, 1985.

ADDRESSES: Copies of the proposed 107 redesignation and the accompanying support documents are available for public inspection during normal business hours at the following locations:

U.S. Environmental Protection Agency,
Region III, Air Program Branch, 841
Chestnut Building, Philadelphia, PA
19107, Attn: Patricia Guaghan (3AM13)
Virginia State Air Pollution Control
Board, Room 801, Ninth Street Office
Building, Richmond, Virginia 23219,
Attn: James Watson

All comments on the proposed revision submitted within 30 days of this Notice will be considered and should be addressed to Mr. David L. Arnold, Chief, DELMARVA/DC Section at the above EPA Region III address. Please reference the EPA Docket Number found in the heading of this Notice.

FOR FURTHER INFORMATION CONTACT:
Harold A. Frankford, (215) 597-1325 or
Cynthia H. Stahl, (215) 597-9337 at the
Region III address above.

SUPPLEMENTARY INFORMATION: On November 20, 1984, the Commonwealth of Virginia State Air Pollution Control Board submitted a request to redesignate three municipalities in the Northern Virginia portion of the National Capital Interstate AQCR as attainment areas for carbon monoxide (CO) under section 107 of the Clean Air Act. These municipalities are Alexandria City, Arlington County, and Fairfax County. However, recent data shows violations of the 8-hour CO standard in Alexandria City and Arlington County. Therefore, on March 18, 1985 Virginia requested that EPA only consider Fairfax County for redesignation.

This proposed redesignation would change the carbon monoxide classification from "Does not meet primary standards" to "Cannot be classified or better than national standards" under 40 CFR 81.347 for Fairfax County. All other air quality designations for carbon monoxide remain unchanged.

There are four monitoring stations in Fairfax County; two, inside the Beltway and two, outside the Beltway. The air quality data from January 1980 through December 1984 submitted by the Commonwealth show that none of the monitoring stations in this county show violations of National Ambient Air Quality Standards (NAAQS). EPA has examined the air quality data collected from the monitoring sites on which this redesignation request is based and has determined that the data were collected in accordance with all EPA requirements. Accordingly, EPA is proposing approval of the Commonwealth's request for redesignation of Fairfax County with respect to CO.

In addition, EPA has approved the CO control strategy applicable to Fairfax County as part of the federally-enforceable Virginia SIP. See 49 FR 3083 (1984). This redesignation does not change any requirements of Virginia's approved SIP.

Conclusion

The Regional Administrator's decision to propose approval of the section 107 redesignation for Fairfax County was based on a determination that it meets the requirements of section 107 of the Clean Air Act and current EPA policy pertaining to redesignation requests.

The public is invited to submit comments, to the address stated above, on whether or not the proposed section 107 redesignation of Fairfax County in Northern Virginia should be allowed.

The Office of Management and Budget has exempted this rule from the

requirements of section 3 of Executive Order 12291.

Under 5 U.S.C. 605(b), the Administrator has certified that the redesignation will not have a significant economic impact on a substantial number of small entities. See 46 FR 8709.

List of Subjects in 40 CFR Part 81

Air pollution control, National parks, Wilderness areas, Intergovernmental relations.

Authority: 42 U.S.C. 7407.

Dated: March 22, 1985.

Stanley L. Laskowski,

Regional Administrator.

[FR Doc. 85-9201 Filed 4-16-85; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 180

[OPP-300127; FRL-2818-7]

Linoleic Diethanolamide; Proposed Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes that linoleic diethanolamide be exempted from the requirement of a tolerance when used as an inert ingredient as a surfactant in pesticide formulations applied to growing crops only. This proposed regulation was requested by Finetex, Inc.

DATE: Comments, identified by the document control number [OPP-300127], must be received on or before May 17, 1985.

ADDRESS: Written comments by mail to: Information Services Section, Program Management and Support Division (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

In person, bring comments to: Registration Support and Emergency Response Branch, Registration Division (TS-767C), Environmental Protection Agency, Rm. 716, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submitted for

inclusion in the public record.

Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 236 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT:

By mail: N. Bhushan Mandava, Registration Support and Emergency Response Branch, Registration Division (TS-767C), Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

Office location and telephone number: Rm. 724A, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703-557-7700).

SUPPLEMENTARY INFORMATION: At the request of Finetex, Inc., the Administrator proposes to amend 40 CFR 180.1001(d) by establishing an exemption from the requirement of a tolerance for linoleic diethanolamide when used as a surfactant in pesticide formulations.

Inert ingredients are all ingredients which are not active ingredients as defined in 40 CFR 162.3(c), and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting and spreading agents; and propellants in aerosol dispensers; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active.

Preambles to proposed rulemaking documents of this nature include the common or chemical name of the substance under consideration, the name and address of the firm making the request for the exemption, and toxicological and other scientific bases used in arriving at a conclusion of safety in support of the exemption.

Name of inert ingredient. Linoleic diethanolamide.

Name and address of requestor. Finetex, Inc., Elmwood Park, NJ 07470.

Bases for approval. 1. The related compound *N,N*-bis-(2-hydroxyethyl) dedecanamide is cleared under 21 CFR 178.3130 for use as an antistatic and/or antifogging agent in food-packaging materials.

2. The linoleic diethanolamide consists of linoleic acid and

diethanolamine, which are the most likely biodegradable products.

3. Linoleic acid is generally regarded as safe under 21 CFR 182.5065 as a dietary supplement and under 21 CFR 182.8065 as a nutrient.

4. Diethanolamine is cleared under 21 CFR 176.170 for use as components of paper and paperboard in contact with aqueous and fatty foods.

5. Diethanolamine is cleared under 40 CFR 180.1001(d) for use as a stabilizer, inhibitor for formulations used before crop emerges from soil.

Based on the above information, and review of its use, it has been found that, when used in accordance with good agricultural practices, this ingredient is useful and does not pose a hazard to humans or the environment. It is concluded, therefore, that the proposed amendment to 40 CFR Part 180 will protect the public health, and it is proposed that the regulation be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this notice in the Federal Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulations. Comments must bear a notation indicating the document control number [OPP-300127]. All written comments filed in response to this petition will be available in the Information Services Section, at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

Sec. 408(e), 68 Stat. 514 (21 U.S.C. 346a(e))

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: April 5, 1985.

Robert V. Brown,

Deputy Director, Registration Division, Office of Pesticide Programs.

PART 180—[AMENDED]

Therefore, it is proposed that 40 CFR 180.1001(d) be amended by adding and alphabetically inserting the inert ingredient, to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

(d) * * *

Inert ingredients	Limits	Uses
Linoleic (CAS Reg. No. 56863-02-6).	diethanolamide	Surfactant.

[FR Doc. 85-9063 Filed 4-16-85; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 180

[PP 00000/P364; FRL-2818-9]

Sodium Metasilicate and Sodium Propionate; Proposed Amendments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule.

SUMMARY: This document proposes to add sodium metasilicate and expand the exemption for sodium propionate for the additional use as a plant desiccant in the pesticide chemicals listed as generally recognized as safe (GRAS) when used as plant desiccants for the purposes of section 408(a) of the Federal Food, Drug, and Cosmetic Act. These proposed amendments were requested by the PQ Corp.

DATE: Comments, identified by the document control number [00000/P364], must be received on or before May 17, 1985.

ADDRESS: Written comments by mail to: Information Service Section, Program Management and Support Division (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

In person, bring comments to: Rm. 716, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part of all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 236 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT:

By mail: N. Bhushan Mandava, Registration Support and Emergency Response Branch, Registration Division (TS-767C), Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

Office location and telephone number: Rm. 724A, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703-557-7700).

SUPPLEMENTARY INFORMATION: This proposed rule is sought in conjunction with the expected use of a mixture of sodium metasilicate, sodium propionate, and sodium carbonate for the purpose of accelerating the field drying (desiccation) of freshly cut hay. Sodium metasilicate and sodium propionate are currently exempt from the requirement of a tolerance under 40 CFR 180.1001(c) when used in accordance with good agricultural practices as inert (or occasionally active) ingredients for use as surfactants, emulsifiers, wetting agents, dispersing agents, buffers (sodium metasilicate), and preservatives for formulations (sodium propionate) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. Sodium propionate is cleared from the requirement of a tolerance under 40 CFR 180.1015 when used as a fungicide in the production of garlic and for postharvest application as a preservative on salad greens and vegetables intended for consumption as salads. Sodium propionate is currently cleared under 40 CFR 180.2(a) as being generally recognized as safe when used as a postharvest fungicide.

Based on the long history of safe use of these chemicals in foods and on their GRAS status under 21 CFR 184.1769a (proposed 48 FR 18831; April 26, 1983 [sodium metasilicate]) and 21 CFR 182.3784 (sodium propionate), the

Agency concludes that neither material should be considered as poisonous or deleterious, and that they are recognized as safe pursuant to 40 CFR 180.2.

Based on the information considered by the Agency, the Agency concludes that the proposed regulation would protect the public health. It is proposed, therefore, that the regulation be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this notice in the *Federal Register* that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 00000/P364]. All written comments filed in response to this petition will be available in the Information Services Section, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the *Federal Register* of May 4, 1981 (46 FR 24950).

(Sec. 408(e), 68 Stat. 514 (21 U.S.C. 346a(e)))

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: April 5, 1985.

Robert V. Brown,

Deputy Director, Registration Division, Office of Pesticide Programs.

PART 180—[AMENDED]

Therefore, it is proposed that 40 CFR 180.2(a) be revised by adding alphabetically an entry for sodium

metasilicate and expanding the use for sodium propionate to include its use as a plant desiccant. As revised, § 180.2(a) reads as follows:

§180.2 Pesticide chemicals considered safe.

(a) As a general rule, pesticide chemicals other than benzaldehyde (when used as a bee repellent in the harvesting of honey), ferrous sulfate, lime, lime-sulfur, potassium carbonate, potassium polysulfide, potassium sorbate, sodium carbonate, sodium chloride, sodium hypochlorite, sodium polysulfide, sodium sesquicarbonate, sorbic acid, sulfur, and, when used as plant desiccants, sodium metasilicate (not to exceed 4 percent by weight in aqueous solution) and sodium propionate, and when used as postharvest fungicides, citric acid, fumaric acid, oil of lemon, oil of orange, sodium benzoate, and sodium propionate are not for the purposes of section 408(a) of the Act generally recognized as safe.

[FR Doc. 85-9081 Filed 4-16-85; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 52

[A-6-FRL-2818-3]

Approval and Promulgation of State Implementation Plan; Reopening of Comment Period: Texas

AGENCY: Environmental Protection Agency.

ACTION: Notice of reopening of comment period.

SUMMARY: On January 4, 1985, at 50 FR 493, the Environmental Protection Agency (EPA) proposed to promulgate a federal compliance date for the Texas Lead State Implementation Plan (SIP) for El Paso County for compliance with certain lead pollution control measures at the ASARCO smelter in El Paso, Texas. On February 1, 1985, and February 4, 1985, ASARCO Incorporated submitted comments on EPA's proposed rulemaking. In addition, ASARCO requested that a public hearing be held and the comment period be extended for an additional 30 days. In a letter dated March 7, 1985, ASARCO withdrew its request for a public hearing and reiterated the request to reopen the comment period. This notice announces that the comment period is reopened for 30 days.

DATE: Comments must be received by May 17, 1985.

ADDRESSES: The rulemaking docket (No. 6A-84-01) may be inspected at the following locations between 8:00 a.m. and 4:40 p.m. on weekdays, and a reasonable fee may be charged for copying.

U.S. Environmental Protection Agency, Central Docket Section, West Tower, Lobby, Gallery No. 1, 401 M Street, S.W., Washington, D.C. 20460

U.S. Environmental Protection Agency, Region 6, Library, 1201 Elm Street, 28th Floor, Interfirst Two Building, Dallas, Texas 75270

Copies of EPA's technical support document may also be inspected in El Paso, Texas at the following location: El Paso City Health Department, 222 South Campbell, El Paso, Texas 79901.

FOR FURTHER INFORMATION CONTACT:

John R. Hepola, Chief, State Implementation Plan Section, Air Branch, U.S. EPA, Region 6, 1201 Elm Street, Dallas, Texas 75270, telephone (214) 767-1518, (FTS) 729-1518.

SUPPLEMENTARY INFORMATION: Under the Clean Air Act, on January 4, 1985, at 50 FR 493, EPA proposed to promulgate a federal compliance date for the Texas Lead State Implementation Plan (SIP) for El Paso County for compliance with certain lead air pollution control measures at the ASARCO smelter in El Paso, Texas. That action was in response to a court ordered schedule resulting from a Settlement Agreement reached on July 26, 1983, between EPA and the Natural Resources Defense Council, Inc. (NRDC et al v. Ruckelshaus et al, Civil Action No. 82-2137) in the U.S. District Court for the District of Columbia. The State of Texas submitted a final lead SIP for El Paso on June 29, 1984. EPA approved it on August 13, 1984, (49 FR 32184), except for a disapproval of one compliance date which the State had included in the SIP. For SIPs or portions of SIPs which EPA has disapproved, EPA is required by the Settlement Agreement to propose a federal SIP by October 1, 1984. The January 4, 1985, notice proposed a federal compliance date for the installation of certain control measures required by the Texas lead SIP for El Paso, requested public comments on EPA's proposed action and offered the opportunity to request a public hearing.

On February 1, 1985, and February 4, 1985, ASARCO Incorporated submitted comments regarding EPA's proposed action of January 4, 1985. In addition, ASARCO requested that a public

hearing be held and the comment periods be extended for an additional 30 days. In a letter dated March 7, 1985, ASARCO withdrew its request for a public hearing and reiterated the request to reopen the comment period.

This notice announces that EPA will reopen the public comment period for an additional 30 days.

List of Subjects in 40 CFR Part 52

Air pollution control, Lead.

(Sec. 110, Clean Air Act)

Dated: April 4, 1985.

Dick Whittington,

Regional Administrator.

[FR Doc. 85-8960 Filed 4-16-85; 8:45 am]

BILLING CODE 6640-50-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 67

[Docket No. FEMA-6625]

Addendum to Proposed Flood Elevation Determinations; Maryland

AGENCY: Federal Emergency Management Agency.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the City of Fruitland, Wicomico County, Maryland.

Due to recent engineering review, this proposed rule would augment the proposed determinations of base (100-year) flood elevations published in the Federal Register at 49 FR 40915 on October 18, 1984, and hence would supersede that previously published proposed rules.

DATES: The period for comment will be thirty (30) days following the second publication of this notice in a newspaper of local circulation in each community.

ADDRESSES: Maps and other information showing the detailed outlines of the floodprone areas and the proposed flood elevations are available for review at the Fruitland City Hall, Fruitland, Maryland.

Send comments to: Honorable Rick Pollitt, Fruitland City Manager, P.O. Box F, Fruitland, Maryland 21826.

FOR FURTHER INFORMATION CONTACT: John L. Matticks, Acting Chief, Risk Studies Division, Federal Insurance Administration, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-2767.

SUPPLEMENTARY INFORMATION: Proposed base (100-year) flood elevations are listed below for selected locations in the City of Fruitland, in accordance with Section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added Section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448)), 42 U.S.C. 4001-4128, and 44 CFR 67.4(a).

These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

List of Subjects in 44 CFR Part 67

Food insurance, Flood plains.

The proposed base (100-year) flood elevations are:

Source of flooding	Location	#Depth in feet above ground. Elevation in feet (NGVD)
Tuxants Branch	At downstream corporate limits.	*8
	At upstream side of Covered Bridge Road.	*16
	At upstream side of South Camden Avenue.	*21
Slab Bridge Creek	At downstream corporate limits.	*22
	At upstream corporate limits.	*22
Sharps Creek (Tidal Flooding from Wicomico River).	At downstream corporate limits.	*8
	Approximately 1,900 feet upstream of corporate limits.	*6

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; 42 U.S.C. 4001-4128; Executive Order 12127, 44 FR 19367; and delegation of authority to the Administrator)

Issued: April 4, 1985.

Jeffrey S. Bragg,

Administrator, Federal Insurance Administration.

[FR Doc. 85-9182 Filed 4-16-85; 8:45 am]

BILLING CODE 6718-02-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Ch. I

[CC Docket No. 85-88; FCC 85-146]

Detariffing of Billing and Collection Services

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The notice proposes to detariff billing and collection services provided by local exchange carriers (LEC) to interexchange carriers (IC) and also solicits comment on the jurisdictional and technical aspects of local cut-offs, or denial of local exchange service for nonpayment of interstate toll charges. The proposed action is necessary because Title II regulation does not seem appropriate for billing and collection insofar as it is essentially a financial and administrative service. Furthermore, to the extent billing and collection services are subject to competition, market forces should be able to supplant tariff regulation. The intended effects of the proposed action are to give LECs more flexibility in responding to the billing needs of ICs while also fostering the growth of competition in the billing and collection market and to eliminate unnecessary regulations.

DATES: Comments regarding the notice are due May 10, 1985; replies are due May 24, 1985.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Barry Lambergman, (202) 632-6917.

SUPPLEMENTARY INFORMATION:

Notice of Proposed Rulemaking.

In the matter of detariffing of billing and collection services; CC Docket No. 85-88, FCC 85-140.

Adopted: March 28, 1985.

Released April 9, 1985.

By the Commission:

I. Introduction and Background

1. In this proceeding we propose to detariff billing and collection services.¹

¹ Billing and collection, in this context, refers to a service provided by a local exchange carrier to an interexchange carrier (IC), whereby the former bills and collects from end users subscribing to an IC's service. More specifically, this service includes recording IC message detail, aggregating the details to create individual messages (a completed call originated by an IC's end user), applying the IC's rates to such messages, processing these rated messages into customer invoice form, mailing bills,

Continued

From the outset of the Commission's brief regulatory experience with billing and collection, we have expressed doubt as to the necessity of subjecting such services to regulation under Title II of the Communications Act, 47 U.S.C. 201 *et seq.*² These misgivings were confirmed when the Commission encountered difficulties in reviewing the billing and collection section of the access tariffs.³ The difficulties stemmed from the Commission's lack of experience in regulating billing and collection⁴ and the fact that billing and collection does not seem to be a communications service *per se*. It appeared to us that to the extent billing and collection is, or at least has the potential to become, a competitive service, marketplace regulation should be able to supplant tariff regulation. Hence, we decided to institute a proceeding to examine the possibility of detariffing billing and collection services.⁵

2. Billing and collection is presently offered under tariff to accommodate a Modification of Final Judgment (MFJ)⁶ requirement that if a Bell Operating Company (BOC) offers such service to even one IC, the charge must be included in the BOC's access tariff. Because only common carrier services can be tariffed, however, we required that an exchange carrier offering a billing and collection service to one IC must offer the same service to all ICs.⁷ Although we initially declined to impose a rate of return constraint on the billing and collection rate element,⁸ the level of

the proposed charges gave us cause to reconsider that decision.⁹ Anticipating that the American Telephone and Telegraph Company (AT&T) would pass these excessive billing charges along to long distance customers, we decided to limit exchange carriers to a return of no more than 12.75 percent on billing and collection service.¹⁰

3. One issue raised by the billing and collection tariffs which has been of particular concern to us, and which to a large extent is at the fulcrum of this proceeding, is the so-called local cut-off problem: that is, denial of local exchange service for nonpayment of IC service charges. In the *February 17 Order*,¹¹ we questioned the reasonableness of this practice because in the post-divestiture era local and long distance services are generally no longer provided by related companies. The exchange carrier's relationship to the end user with respect to the service provided by the IC is merely that of billing agent or holder of IC receivables. We noted that a serious question of fairness to end users is raised where a subscriber's local telephone service is placed in jeopardy by an exchange carrier acting in such a capacity. At the same time, however, we recognized that there may be technical limitations inherent in certain types of switching equipment which could effectively preclude compliance with a prohibition on local cut-offs. Hence, we required carriers to submit technical justification for this provision by showing what operational restraints would prevent separate termination of local and interexchange service.

4. The justification proffered by the carriers was found to be materially incomplete. Thus, we required that all local cut-off provisions be deleted from the tariffs.¹² Carriers subsequently applied for waivers¹³ of this prohibition, further alleging that the technical limitations of most switching systems make separate screening and blocking of interstate toll calls impossible in some end offices and difficult in others. They also maintained that these technical

problems are compounded by administrative burdens, given the inability of current mechanized billing systems to process partial payments for multiple balances due on a single customer account. Moreover, AT&T contended that unless carriers were permitted to continue local cut-offs, AT&T uncollectibles would double, causing a serious decline in its rate of return. Given this information we decided to modify our treatment of this issue on a temporary basis by allowing local cut-offs where permitted by state authority.¹⁴

II. Discussion

5. We approach this subject from the standpoint of our role as a regulator of communications services. Inasmuch as billing and collection is essentially a financial and administrative service, it may not be an appropriate subject for Title II regulation. On the other hand, to the extent that the billing and collection function has an effect on services which are within our purview, we do have a regulatory interest and must deal with it accordingly. For example, the fact that ICs pass billing costs along to end users by bundling them into long distance rates led us to impose a rate of return constraint on billing and collection services. Indeed, the high level of the charges proposed prior to our setting a return is perhaps evidence that carriers do not view billing and collection as a competitive service at the present time. Nevertheless, any need for such regulation should be short-term. In the immediate aftermath of divestiture, AT&T has little choice but to continue its billing arrangements with the BOCs. There are already indications, however, that AT&T is developing its own billing system.¹⁵ ICs other than AT&T have

collecting payments, accepting customer deposits, handling customer inquiries and investigating billing evasion activities.

² See MTS/WATS Market Structure (Phase I), CC Docket No. 78-72, 97 FCC 2d 682, 741 (1984) (*First Reconsideration Order*).

³ See Investigation of Access and Divestiture Related Tariffs, CC Docket No. 83-1145, 97 FCC 2d 1082, 1283 (1984) (*February 17 Order*).

⁴ Prior to the divestiture of the Bell System, billing and collection was traditionally performed either by the carrier itself or by contract. Consequently, there was virtually no historical data by which to judge the reasonableness of the proposed rates and practices.

⁵ *February 17 Order*, 97 FCC 2d at 1285.

⁶ United States v. AT&T, 552 F. Supp. 131, 234 (D.D.C. 1982), *aff'd sub nom. Maryland v. United States*, 460 U.S. 1001 (1983).

⁷ See Section 69.114(a) of the Commission's Rules, 47 CFR 69.114(a). See also MTS/WATS Market Structure, CC Docket No. 78-72, Phase I, 93 FCC 2d 241, 313 (1983) (*Access Charge Order*).

⁸ *Access Charge Order*, 393 FCC 2d at 314. Section 69.114(b) of the Commission's Rules, 47 CFR 69.114(b), did require, however, that charges for these services be both reasonable and nondiscriminatory. See also *First Reconsideration Order*, 97 FCC 2d at 742.

⁹ Representatives of the exchange carriers had informed us that, at the filed rates, industry earnings for billing and collection would be about \$479 million above a 12.75 percent return. Investigation of Access and Divestiture Related Tariffs, CC Docket No. 83-1145, Phase I, and MTS/WATS Market Structure, CC Docket No. 78-72, Phase I, 49 FR 23924 (June 8, 1984), at para. 62.

¹⁰ *Id.* at para. 83.

¹¹ 97 FCC 2d at 1289.

¹² Investigation of Access and Divestiture Related Tariffs, CC Docket No. 83-1145, Phase I, FCC 84-188, released Apr. 27, 1984, at 8-2 (*April 27 Order*).

¹³ We had invited carriers to apply for temporary waivers provided that a complete technical showing could be made in support thereof.

¹⁴ Investigation of Access and Divestiture Related Tariffs, CC Docket No. 83-1145, Phase I, Mimeo No. 4246, released May 16, 1984 (*Waiver Order*). Since state rules would apply while this matter was under review, we decided there was no need for any reference to local cut-offs in tariffs on file with this Commission.

¹⁵ For example, AT&T recently dropped billing inquiry service, a sub-offering of billing and collection service, provided by the New York Telephone Company. In fact, the Joint Board recently noted that AT&T had stated that it planned to initiate its own billing inquiry service in 22 states by January 1, 1985 and to complete the transition to use of its own billing inquiry centers for the areas served by the BOCs by August 1985. AT&T has stated that it is taking this action primarily for customer relations reasons. See Recommended Interim Order and Request for Comments, CC Docket Nos. 78-72 and 80-286, Mimeo No. 3400, released Mar. 25, 1985, at para. 4 (*Joint Board Order*). In addition, according to the Mountain States Telephone and Telegraph Company, AT&T has indicated that it is considering providing its own billing and collection services for its largest

Continued

never had to rely on local telephone companies to do their billing. They have either set up their own systems or contracted with commercial billing firms such as major credit card companies to do it for them.

6. Hence, there appears to be no reason to believe that exchange carriers would be able to extract monopoly profits from billing and collection services if those services are detariffed. As we recognized in the *First Reconsideration Order*, billing and collection performed for third parties is not inherently part of a local exchange carrier's bottleneck monopoly.¹⁶ Because billing and collection functions can be performed internally or be obtained from competing vendors, we expect that market forces can readily respond to excessive rates or unreasonable practices. We therefore seek comment on the extent to which competition in billing for interstate telephone services presently exists or can be expected to develop.

7. The ability of exchange carriers to impose local cut-offs for nonpayment of IC services could conceivably hinder the development of such competition by deterring market entry by other billing agencies. While we are not prepared to say that this ability would enable carriers to monopolize, or even acquire a larger share of, the broader commercial billing market, we do believe that use of their leverage over a monopoly communications service to coerce payment represents an abuse of their power to control access to such monopoly service. Inasmuch as billing and collection is not inherently a communications service, the systems set up by the carriers for the purpose of billing telephone calls can be used to bill other products and services as well.¹⁷ Thus, for example, a consumer's local telephone service could be discontinued for nonpayment of a department store bill. In our view it is unfair for a person's local telephone service to be terminated for nonpayment of an unrelated service when in fact he is paying his local service bill.

customers and certain smaller customers. Mountain States Telephone and Telegraph Company Special Permission Application No. 32, filed Feb. 14, 1985. Cf. Procedures for Implementing the Detariffing of Customer Premises Equipment and Enhanced Services (Second Computer Inquiry), CC Docket No. 81-893, Memorandum Opinion and Order on Reconsideration, FCC 85-35 (released Jan. 29, 1985) at para. 61 & n.82 (AT&T phasing out reliance on BOCs for embedded customer premises equipment billing services).

¹⁶ *First Reconsideration Order*, 97 FCC 2d at 742.

¹⁷ To the extent that carriers do perform billing and collection for noncommunications services they may be subject to other state or federal regulations.

8. A number of the pleadings concerning reconsideration of the *April 27 Order* and the *Waiver Order* took the position that the Commission should defer to state regulatory authorities with respect to local cut-offs because the issues involved are better suited to state resolution.¹⁸ AT&T, on the other hand, argued that there should be a federal solution to this problem in order to ensure consistency.¹⁹ As matters stand, we have deferred to the states on a temporary basis. We would like to receive additional comment as to whether this approach should be adopted on a permanent basis or whether there is a federal interest in imposing a nationwide prohibition of local cut-offs for nonpayment of charges unrelated to the local carrier's service. Such a prohibition would apply independent of any detariffing action the Commission may decide to take. We also solicit further information from carriers as to their technical ability to perform interstate-only cut-offs. More specifically, information is sought as to the scheduled availability of different generations of software which would make it possible to discontinue toll service without also discontinuing local service, and taking that one step further, to discontinue interstate toll separately from intrastate toll service.²⁰ Similarly, we will need information as to software which allows carriers to block access to an individual IC without also restricting access to other ICs with points of presence in the local access and transport area involved.

9. Although we tentatively conclude that Title II regulation may not be necessary for billing and collection,²¹ at

¹⁸ See Petition for Reconsideration of the New York State Department of Public Service, CC Docket No. 83-1145, June 8, 1984; Reply Comments of the Telephone Companies, CC Docket No. 83-1145, Aug. 1, 1984; Comments of Bell Atlantic, CC Docket No. 83-1145, July 17, 1984.

¹⁹ See Petition for Partial Reconsideration of AT&T, CC Docket No. 83-1145, May 7, 1984.

²⁰ To the extent that these might not be severable, we might find it necessary to preempt state authority should we find that there is a federal interest in addressing this issue. There is the possibility, however, of referring such a matter to a Federal-State Joint Board under section 410(c) of the Communications Act, 47 U.S.C. 410(c), which could then propose uniform rules with respect to service disconnections.

²¹ To the extent that it may be argued that detariffing would be inconsistent with the MFJ, we are of the view that the court did not intend to impose a regulatory obligation upon this Commission which conflicts with our statutory mandate. We suspect that the court simply saw tariffs as a mechanism for assuring that ICs have nondiscriminatory access to billing and collection services and that the rates BOCs charged AT&T for these services fully covered costs.

least not to the extent that it is considered a financial service, the billing and collection rate element does include one function which appears to be directly ancillary to a communications service—recording.²² As noted in the *February 17 Order*, "the facilities involved in recording are clearly germane to the telephone company. To the extent that recording is performed in the normal course of network operations, there would be a wasteful duplication of facilities were it to be done by some other entity."²³ Therefore, because the recording function does not seem to be potentially competitive and does exhibit some of the characteristics of a communications service, we propose to draw the line here and keep the recording function under tariff.

10. As to the mechanics of detariffing, carriers would, of course, be required to remove the costs associated with billing and collection from their regulated accounts and revenue requirements.²⁴ In this regard, we seek comment on whether all carriers should simply be required to maintain separate accounting for their billing and collection activities or whether the BOCs (as dominant carriers) should be required to offer these detariffed services through a separate subsidiary. We also solicit comment on the types of separate accounting requirements which should be established.

11. Furthermore, the removal of billing and collection costs from carriers' rate bases and operating expense accounts may raise questions with respect to jurisdictional separations. The Federal-State Joint Board recently solicited comments concerning permanent changes in the procedures for allocating Account 645, Local Commercial Operations (which are reflected in the charges for billing inquiry service), as well as "the need for changes in the procedures for the allocation and recovery of Account 662, Accounting Department costs, in light of the post-divestiture environment in which AT&T may discontinue its use of the billing

²² Recording is the entering on magnetic tape or other acceptable medium of the details of IC messages originating through Switched Access Service. The assembly and editing function then identifies the message details for a particular IC, aggregates the details to create individual messages and verifies that the data required for rating is present.

²³ *February 17 Order*, 97 FCC 2d at 1284-85.

²⁴ To the extent that carriers jointly bill their own services and IC services in a single mailing there will be joint and common costs such as postage and envelopes. We seek comment on how the allocation of such costs should be treated.

and collection services offered by the local exchange companies."²⁵

Comments and replies in that proceeding are due April 22 and May 13, 1985, respectively. This should give interested parties in the present proceeding ample time to comment before the Joint Board on any separations changes that might be appropriate in light of the action we are proposing herein.²⁶

12. We propose to make detariffing permissive initially, but mandatory at a later date so that all carriers will be required to withdraw their billing and collection tariffs by a date to be determined later in this proceeding.²⁷ Carriers will be free to withdraw their tariffs any time during this initial period. We propose, however, that carriers choosing to keep tariffs on file at the Commission during the permissive stage will be subject to the same notice and cost support requirements as are applicable to other tariffs and will be limited to a fixed rate of return.

13. Regardless of whether carriers withdraw their tariffs during the permissive or mandatory stage, there will still be the possibility of residual regulation through the complaint process under Section 208 of the Act, 47 U.S.C. 208. Such complaints, however, would have to be limited to billing problems that have a direct and immediate effect on a communications service. Our expectation is that most billing-related complaints, such as unlawfully high interest rates, will be handled in a different forum.²⁸

14. This Notice of Proposed Rulemaking is being issued to determine whether the detariffing of billing and collection services provided by local exchange carriers to ICs is just, fair and reasonable, and in the public interest. We expect to develop in this notice and comment rulemaking all the relevant material and probative data and information needed to make the public interest determination.²⁹

²⁵ Joint Board Order at para. 25.

²⁶ In their filings before the Joint Board, interested parties need not limit their comments solely to the allocation and recovery of costs in Account 662. Any other separations issues raised by our proposals in this proceeding should also be addressed in the Joint Board filings.

²⁷ We seek comment as to what would be a reasonable time frame for this purpose.

²⁸ Should a dispute be properly before us, we might require under Section 211(b) of the Act, 47 U.S.C. 211(b), that any relevant contracts be filed with the Commission.

²⁹ The Joint Board recently recommended that the Commission adopt interim separations procedures to prevent a sudden and substantial shift of costs to the intrastate jurisdiction as a result of AT&T's

III. Ordering Clauses

15. Accordingly, It is ordered, that a rulemaking proceeding is instituted to determine whether the detariffing of billing and collection services is just, fair and reasonable, and in the public interest. This proceeding is instituted pursuant to sections 2(a), 4(i), 4(j), 201, 202, 203, 205, and 403 of the Communications Act, 47 U.S.C. 152(a), 154(i), 154(j), 201, 202, 203, 205, and 403.

16. It is further ordered, that interested persons may file written comments on or before May 10, 1985 and reply comments on or before May 24, 1985. In reaching its decision in this matter the Commission may take into consideration information and ideas not contained in the comments, provided that such information or a writing indicating the nature and source of such information is placed in the public file, and provided that the fact of the Commission's reliance on such information is noted in the Report and Order. All comments and reply comments shall be filed in accordance with §§ 1.411-1.419 of the Commission's Rules, 47 CFR 1.411-1.419. Materials filed in this proceeding will be available for public inspection during regular business hours in the Commission's Public Reference Room at its headquarters at 1919 M St., N.W., Washington, D.C.

17. It is further ordered, that for purposes of this non-restricted notice and comment rulemaking proceeding, members of the public are advised that *ex parte* contacts are permitted from the time the Commission adopts a notice of proposed rulemaking until the time a public notice is issued stating that a substantive disposition of the matter is to be considered at a forthcoming meeting. In general, an *ex parte* presentation is any written or oral communication (other than formal written comments or pleadings and formal oral arguments) between a

decision to implement its own billing inquiry service and discontinue use of these services offered by the BOCs. Deregulation of billing inquiry as well as other billing and collection services should not complicate potential cost allocation and recovery issues associated with AT&T's discontinuation of these services. Rather, deregulation will give the BOCs greater flexibility in structuring and pricing these service offerings, and enhance their ability to attract and retain customers.

As previously noted, the Joint Board has requested comments concerning the need for changes in the procedures for allocating the accounts related to the provision of billing inquiry and other billing and collection services. See para. 11, *supra*. Any separations questions raised by the possible deregulation of these services will be considered in the context of the Joint Board proceeding.

person outside the Commission and a Commissioner or a member of the Commission's staff which addresses the merits of the proceeding. Any person who submits a written *ex parte* presentation must serve a copy of that presentation on the Commission's Secretary for inclusion in the public file. Any person who makes an oral *ex parte* presentation addressing matters not fully covered in any previously-filed written comments for the proceeding must prepare a written summary of that presentation; on the day of oral presentation, that written summary must be served on the Commission's Secretary for inclusion in the public file, with a copy to the Commission official receiving the oral presentation. Each *ex parte* presentation described above must state on its face that the Secretary has been served, and must also state by docket number the proceeding of which it relates. See generally § 1.1231 of the Commission's Rules, 47 CFR 1.1231.

18. Pursuant to section 605(b) of the Regulatory Flexibility Act (Pub. L. 96-354) it is certified, that sections 603 and 604 of the Act do not apply to this proceeding because this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. See 5 U.S.C. 603, 604 605(b). It is our expectation that marketplace alternatives will afford interexchange carriers adequate protection against any unreasonably high rates which may be set by local exchange carriers for billing and collection services. Further, we propose to dispose of the issue of local service disconnections for nonpayment of interstate toll charges in such a way that the interests of end users will be accommodated in the detariffing process.

19. It is further ordered, that the Secretary shall cause this Notice of Proposed Rulemaking to be published in the Federal Register.

20. It is further ordered, pursuant to section 220(i) of the Communications Act, 47 U.S.C. 220(i), that the Secretary shall serve a copy of this Notice on each state commission.

(Secs. 4, 303, 48 stat., as amended, 1066, 1082; 47 U.S.C. 154, 303)

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc. 85-9247 Filed 4-16-85; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL COMMUNICATIONS
COMMISSION

47 CFR Part 97

[PR Docket No. 85-104; RM-4872; FCC 85-168]

Telephony Operation in the 7075-7100
kHz Frequency Band in the Caribbean
Insular AreasAGENCY: Federal Communications
Commission.

ACTION: Proposed rule.

SUMMARY: This document proposes to allow FCC-licensed amateur operators in the Caribbean Insular Areas to use telephony in the 7075-7100 kHz segment of the 40 meter band. This action is proposed to provide these operators relief from broadcast interference in the 7100-7300 kHz segment of that band and to enable them to communicate with amateur operators in surrounding nations using the 7075-7100 kHz segment for telephony.

DATE: Comments are due by June 17, 1985 and replies by July 17, 1985.

ADDRESS: Federal Communications Commission, 1919 M. Street, NW., Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: John J. Borkowski, Private Radio Bureau, Washington, D.C. 20554, (202) 632-4964.

SUPPLEMENTARY INFORMATION:

List of Subjects in 47 CFR Part 97

Radio.

Proposed Rule making

In the matter of amendment of Part 97 of the Commission's Rules to Permit Telephony Operation in the 7075-7100 kHz Frequency Band in the Caribbean Insular Areas; PR Docket No. 85-104, RM-4872.

Adopted: April 5, 1985.

Released: April 9, 1985.

By the Commission.

Background

1. On November 6, 1984, David Novoa filed a Petition for Rule Making^{1 2} in

¹ On November 19, 1984 petitioner indicated that the North Latitude in his proposed rule should be 19 degrees instead of 17 degrees. We have incorporated this change by proposing a broad rule which would permit telephony operation anywhere outside the continental United States.

² On January 17, 1985, petitioner filed a "Motion Ancillary to Petition" which sought immediate grant of his petition without notice-and-comment proceedings on the basis that the proposed rule is an interpretative rule or a general statement of policy. However, we prefer to allow public comment on expanding operating capabilities in an area. Therefore, this motion is denied.

which he requested that telephony privileges be authorized for General, Advanced and Amateur Extra operators when their stations are in the Caribbean Insular Areas (the Commonwealth of Puerto Rico, Navassa Island or the United States Virgin Islands).³ In support of the petition he stated that FCC-licensed amateurs in the Caribbean are situated similarly to amateurs in Hawaii and Alaska who were recently granted telephony privileges identical to those he has requested.

2. In the *Second Report and Order* in PR Docket No. 82-83, 49 FR 30469 (July 31, 1984), we authorized telephony operation in the 7075-7100 kHz segment of the 40 meter band (7000-7300 kHz) in Hawaii and in areas near Region 3, including Alaska. We did so in order to permit FCC-licensed amateur operators near Region 3 to communicate with amateur operators in Region 3 already authorized for telephony operation in this band. We also sought to provide these amateur operators with relief from the interference they were experiencing from broadcast stations in Regions 1 and 3.

3. Petitioner argues that the Caribbean is now the only area outside of the continental United States under U.S. jurisdiction in which U.S. amateur operators may not operate radio telephony in the 7075-7100 kHz segment. Petitioner further argues that circumstances in the Caribbean are equivalent to those in the Pacific, namely, use of this segment for telephony by surrounding nations and broadcast interference which renders the 7100-7300 kHz segment of the 40 meter band almost useless at night. Mr. Novoa argues that U.S. amateur telephony operation in the 7075-7100 kHz band in the Caribbean would promote international goodwill and would not cause detrimental interference to telegraphy operators in the continental United States because of the limited number of potential users.

Comments

4. We received nine comments upon the Petition for Rule Making, all in support of the petition. The comments were from the DX Club of Puerto Rico, the Puerto Rico Amateur Radio Club, Inc., Ernesto J. Cardona, Hector F. Davila, Frank E. Dobek, Fernando Hernandez, Eduardo Negron, Isaac Novoa and Randall F. Sobol. All the comments concur that interference in

³ Petitioner has also requested telephony operation in these bands for Desecheo Island. Desecheo Island is part of the Commonwealth of Puerto Rico. When we refer to the United States Virgin Islands, we mean the fifty islets and cays which comprise this group.

the Caribbean from broadcast stations makes the 7100-7300 kHz band virtually useless in the Amateur Radio Service, particularly at night. Several commenters stated that almost all emergency, weather and DX nets in the Caribbean are run between 7000 and 7100 kHz in order to avoid broadcast interference. According to these commenters, amateurs in Puerto Rico and the U.S. Virgin Islands are currently excluded from Caribbean emergency nets and drills because they do not operate telephony in the segment most used for this purpose: 7075 to 7100 kHz. All of the comments emphasize that U.S. jurisdictions in the Caribbean are the only locations in the Caribbean where telephony is completely prohibited between 7000 kHz and 7100 kHz. Many commenters agreed that U.S. amateur privileges between 7075 and 7100 kHz would promote international goodwill.

5. Some of the commenters proposed alternative features. In order to insure minimum interference to amateur telegraphy and radioteletyping operations in the continental United States, the Puerto Rico Amateur Radio Club, Inc. would limit the proposed telephony privileges to Advanced and Amateur Extra operators. Isaac Novoa also recommended this approach. Randall F. Sobol recommended expanding the size of the proposed telephony segment to 7050-7100 kHz because authorization is pending for a commercial shortwave station to operate above 7100 kHz. He would also expand the proposed rule to permit telephony in this segment for all amateur stations located outside the continental forty-eight states.

Proposal

6. In view of the above, we propose to expand telephony privileges in the 7075-7100 kHz segment of the 40 meter band to include the Caribbean Insular Areas, as shown in the attached Appendix. We seek comment not only on the proposal itself, but also on the alternatives recommended by the Puerto Rico Amateur Radio Club, Inc., Isaac Novoa and Randall Sobol.

Other Matters

7. For purposes of this non-restricted notice and comment rule making proceeding, members of the public are advised that *ex parte* contacts are permitted from the time the Commission adopts a notice of proposed rule making until the time a public notice is issued stating that a substantive disposition of the matter is to be considered at a forthcoming meeting or until a final order disposing of the matter is adopted

by the Commission, whichever is earlier. In general, an *ex parte* presentation is any written or oral communication (other than formal written comments/pleadings and formal oral arguments) between a person outside the Commission and a Commissioner or a member of the Commission's staff which addresses the merits of the proceeding. Any person who submits a written *ex parte* presentation must serve a copy of that presentation to the Commission's Secretary for inclusion in the public file. Any person who makes an oral *ex parte* presentation addressing matters not fully covered in any previously-filed written comments for the proceeding must prepare a written summary of that presentation; on the day of oral presentation, that written summary must be served on the Commission's Secretary for inclusion in the public file, with a copy to the Commission official receiving the oral presentation. Each *ex parte* presentation described above must state on its face that the Secretary has been served, and must also state by docket number the proceeding to which it relates. See generally, § 1.1231 of the Commission's rules, 47 CFR 1.1231. A summary of the Commission's procedures governing *ex parte* contacts in informal rule making is available from the Commission's Consumer Assistance Office, FCC, Washington, D.C. 20554 (202) 632-7000.

8. Authority for issuance of this Notice is contained in sections 4(i) and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i) and 303(r). Pursuant to applicable procedures set forth in Sections 1.415 and 1.419 of the Commission's Rules (47 CFR 1.415 and 1.419) interested parties may file comments on or before June 17, 1985, and reply comments on or before July 17, 1985. All relevant and timely comments will be considered by the Commission before final action is taken in this proceeding. To file formally in this proceeding, participants must file an original and five copies of all comments, reply comments and supporting comments. If participants want each Commissioner to receive a personal copy of their comments, an original and nine copies must be filed. Comments and reply comments should be sent to Office of the Secretary, Federal Communications Commission, Washington, D.C. 20554. Comments and reply comments will be available for public inspection during regular business hours in the Dockets Reference Room (Room 239) of the Federal Communications Commission, 1919 M Street, NW, Washington, D.C. 20554.

9. The proposal contained herein has been analyzed with respect to the Paperwork Reduction Act of 1980 and found to contain no new or modified form, information collection and/or record keeping, labeling, disclosure, or record retention requirements; and will not increase or decrease burden hours imposed on the public.

10. In accordance with section 605 of the Regulatory Flexibility Act of 1980 (5 U.S.C. 605), we certify that this rule change would not, if promulgated, have a significant economic impact on a substantial number of small entities, because these entities may not use the Amateur Radio Service for commercial radio communication. (See 47 CFR 97.3(b)).

11. It is ordered, That the Petition for Rule Making filed by David Novoa on November 6, 1984 (RM-4872) is granted.

12. It is further ordered, that the Motion Auxiliary to Petition filed by David Novoa on November 19, 1984 is granted.

13. It is further ordered, that the Motion Ancillary to Petition filed by David Novoa on January 17, 1985 is denied.

14. It is further ordered, that the Secretary shall cause a copy of this Notice to be served upon the Chief Counsel for Advocacy of the Small Business Administration.

15. For information concerning this proceeding, contact John J. Borkowski, Federal Communications Commission, Private Radio Bureau, Washington, D.C. 20554 (202) 632-4964.

(Secs. 4, 303, 48 stat., as amended, 1066, 1082; 47 U.S.C. 154, 303)

Federal Communications Commission,
William J. Tricarico,
Secretary.

Appendix

Part 97 of Chapter I of Title 47 of the Code of Federal Regulations would be amended as follows:

1. Paragraph (b)(1) of Section 97.61 would be revised to read:

§ 97.61 Authorized frequencies and emissions.

• • • • •
(b) Limitations:

• • • • •
(1) The use of A3E and F3A in this band is limited to amateur radio stations transmitting from any location other than the forty-eight contiguous states.
• • • • •

[FR Doc. 85-9250 Filed 4-16-85; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 97

[PR Docket No. 85-105; RM-4879; FCC 85-169]

Amateur Radio Service Rules to Permit Automatic Control of Amateur Radio Stations

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the Amateur Radio Service Rules to allow any amateur radio station to be under automatic control, except when transmitting on frequencies below 29.5 MHz and when transmitting third-party traffic. The proposed rule is necessary in order to utilize new technology in the service. The effect of this proposed rule is to encourage greater experimentation in the service, particularly with automatic control of digital communications.

DATES: Comments are due by June 25, 1985 and replies by July 25, 1985.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Maurice J. DePont, Private Radio Bureau, Washington, D.C. 20554, (202) 632-4964.

SUPPLEMENTARY INFORMATION:

List of Subjects in 47 CFR Part 97

Amateur radio, Radio.

Notice of Proposed Rule Making

In the matter of Amendment of Part 97 of the Commission's Rules to permit automatic control of amateur radio stations; PR Docket No. 85-105, RM-4879.

Adopted: April 5, 1985.

Released: April 11, 1985.

By the Commission.

1. Notice of Proposed Rule Making in the above-captioned matter is hereby given.

2. The Commission has received a petition (RM-4879) from the American Radio Relay League, Inc., (ARRL) seeking to amend the Amateur Radio Service Rules to permit automatic control of digital communications on all amateur frequencies above 30 MHz.¹ The ARRL notes that Part 97 currently contains provisions for automatic control of stations in repeater, auxiliary and beacon operation but makes no provision for automatic control of

¹ The ARRL said that it was not requesting automatic control for frequencies below 30 MHz (HF frequencies) because heavy frequency usage below 30 MHz made manual control of digital communications on those frequencies more appropriate.

routine digital communications. In support of its petition, the ARRL states that a variety of digital codes, such as radioteletype, transfer of computer programs, direct computer-to-computer communications and "packet switching" systems lend themselves to a mode of amateur radio transmission where a control operator need not be present. According to the ARRL, present microprocessor and computer technology now routinely present at amateur stations can automatically transmit and receive digital communications, verify receipt of messages and respond to inquiries. The ARRL notes that the use of Computer Based Message Systems (CBMS) are something new in amateur communications and should be encouraged by more experimentation, including automatic control which is both feasible and necessary to facilitate further development in the art of amateur radio. Two timely comments were filed. Both supported the petition for rule making.

3. Automatic control in the Amateur Radio Service has previously been approved for repeater, auxiliary links and beacon operations.² With an evergrowing list of amateur operations where automatic control is permitted, we believe that now may be the appropriate time to expand automatic control to all amateur operations, prohibiting its use only in those situations where there is a justifiable reason why automatic control should not be allowed. Therefore, we invite amateur radio operators in general, and amateurs experienced in automatic control in particular, to submit comments calling to our attention any problems that may arise by expanding automatic control to encompass all amateur radio operations. Our goal is to keep the amateur service abreast of technological developments and to utilize new technology, such as CBMS, where appropriate. On the other hand, we do not want to introduce any innovations into the service which would be disruptive of amateur communications or which would essentially change the character of the service.

4. We propose that any amateur radio station may be under automatic control, except when transmitting on frequencies below 29.5 MHz. As noted earlier, the petitioner did not request automatic

control below 30 MHz. However, since automatic control is already permitted for repeater operation between 29.5-29.7 MHz, it is reasonable to make the lower limit for automatic control 29.5 MHz, rather than 30 MHz.

5. These proposed rule amendments would still prohibit automatic control operation in any instance where the station is transmitting third-party traffic. This is in accord with § 97.79(d) of the amateur rules which specifies that a control operator must always be present when a third party is participating in amateur radio communications.³

6. For purposes of this non-restricted notice and comment rule making proceeding, members of the public are advised that *ex parte* contacts are permitted from the time the Commission adopts a Notice of Proposed Rule Making until the time a public notice is issued stating that a substantive disposition of the matter is to be considered at a forthcoming meeting. In general, an *ex parte* presentation is any written or oral communication (other than formal written comments/pleadings and formal oral arguments) between a person outside the Commission and a Commissioner or a member of the Commission's staff which addresses the merits of the proceeding. Any person who submits a written *ex parte* presentation must serve a copy of that presentation on the Commission's Secretary for inclusion in the public file. Any person who makes an oral *ex parte* presentation, addressing matters not fully covered in any previously-filed comments in the proceeding, must prepare a written summary of that presentation; on the day of the oral presentation, that written summary must be served on the Commission's Secretary for inclusion in the public file, with a copy to the Commission official receiving the oral presentation. Each *ex parte* presentation must also state by docket number the proceeding to which it relates. See generally, § 1.1231 of the Commission's Rules, 47 CFR 1.1231. A summary of the Commission's procedures governing *ex parte* contacts in informal rule makings is available from the Commission's Consumer Assistance Office, FCC, Washington, D.C. 20554, (202) 632-7000.

7. Authority for issuance of this Notice is contained in sections 4(i) and (303) (g) and (r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i) and (303) (g) and (r). Pursuant to applicable procedures set forth in § 1.415, 47 CFR 1.415, of the Commission's Rules,

interested persons may file comments on or before June 25, 1985, and reply comments on or before July 25, 1985. All relevant and timely comments will be considered by the Commission before final action is taken in this proceeding. In reaching its decision, the Commission may take into consideration information and ideas not contained in the comments, provided that such information or a writing indicating the nature and source of such information is placed in the public file, and provided further that the fact of the Commission's reliance on such information is noted in the Report and Order.

8. In accordance with § 1.419 of the Commission's Rules, 47 CFR 1.419, formal participants must file an original and five copies of their comments and other materials. Participants who wish each Commissioner to have a personal copy of their comments should file an original and eleven copies. Members of the general public who wish to express their interest by participating informally may do so by submitting one copy. All comments are given the same consideration, regardless of the number of copies submitted. Each set of comments must state on its face the proceeding to which it relates (PR Docket Number) and should be submitted to: The Secretary, Federal Communications Commission, Washington, D.C. 20554. All documents will be available for public inspection during regular business hours in the Commission's Public Reference Room at its headquarters in Washington, D.C.

9. In accordance with section 605 of the Regulatory Flexibility Act of 1980 (5 U.S.C. 605), the Commission certifies that these rules would not, if promulgated, have a significant economic impact on a substantial number of small entities because these entities may not use the Amateur Radio Service for commercial radiocommunication (see 47 CFR 97.3(b)). In addition, the proposed rules concerning expansion of automatic control in the Amateur Radio Service would not significantly impact on the manufacturers of amateur radio equipment since devices installed to secure the radio equipment from unauthorized use or to detect transmitter malfunction are not usually purchased from such manufacturers.

10. In view of the foregoing, rule making petition RM-4879 filed by the ARRL is granted.

11. It is ordered, That the Secretary shall cause a copy of this Notice to be served upon the Chief Counsel for Advocacy of the Small Business Administration and the Secretary shall

²For automatic control of stations in repeater and auxiliary operation, see Report and Order in Docket No. 20112, adopted June 11, 1975; FCC 75-706; 40 FR 26524, June 24, 1975. For automatic control of beacon operations, see Report and Order in PR Docket No. 81-823, adopted October 21, 1982; FCC 82-455; 47 FR 6702, November 9, 1982.

³See also News Release, Report No. 2028, Mimeo No. 8832, October 25, 1978.

also cause a copy of this Notice to be published in the **Federal Register**.

12. For information concerning this proceeding, contact Maurice J. DePont, Federal Communications Commission, Private Radio Bureau, Washington, D.C. 20554, (202) 632-4964.

(Secs. 4, 303, 48 Stat., as amended, 1066, 1082; 47 U.S.C. 154, 303)

Federal Communications Commission.

William J. Tricarico,

Secretary.

PART 97—[AMENDED]

Appendix

Part 97 of Chapter I of Title 47 of the Code of Federal Regulations would be amended, as follows:

1. Section 97.3(m)(3) would be revised to read:

§ 97.3 Definitions.

(m)

(3) *Automatic control* means the use of devices and procedures for control of an amateur station without the control operator being present at the control point.

2. Section 97.79(b) would be revised to read:

§ 97.79 Control operator requirements.

(b)

(b) Every amateur radio station, when transmitting, must have a control operator. The control operator must be present at the control point of the station, except when the station is transmitting under automatic control. The control operator must be a licensed amateur radio operator or permittee designated by the station licensee. The control operator and the station licensee are both responsible for the proper operation of the station. For purposes of enforcement of the rules of this part, the FCC will presume that the station licensee is the control operator of the station, unless documentation exists to the contrary.

3. A new § 97.80 would be added as follows:

§ 97.80 Operation under automatic control.

(a) An amateur radio station may be operated under automatic control:

(1) When in beacon operation on frequencies 28.20–28.30 MHz; and

(2) When transmitting on frequencies above 29.5 MHz, except when in beacon operation:

MHz: 50.00–50.06; 50.08–54.0; 144.00–144.05;

144.06–148.00; 220.00–220.05; 220.06–222.05; 222.06–225.00; 420.00–432.07; 432.08–450.00.

(b) When under automatic control, devices must be installed and procedures must be implemented which will ensure compliance with the rules when the control operator is not present at the control point of the station.

(c) No amateur radio station may be operated under automatic control while transmitting third-party traffic.

(d) Automatic control of a station must cease upon notification by the Engineer-in-Charge of a Commission field office that the station is transmitting improperly or causing harmful interference to other stations. Automatic operation must not be resumed without prior approval of the Engineer-in-Charge.

§ 97.85 [Amended]

4. Section 97.85(e) would be removed. Paragraphs (f), (g) and (h) would be redesignated as paragraphs (e), (f) and (g), respectively.

§ 97.86 [Amended]

5. Section 97.86(a) would be removed. Paragraphs (b), (c) and (d) would be redesignated as paragraphs (a), (b) and (c), respectively.

§ 97.87 [Amended]

6. Section 97.87 (b) and (c) would be removed. Paragraph (d) would be redesignated as paragraph (b) and paragraph (e) would be redesignated as paragraph (c). In redesignated paragraph (b), the last sentence would be amended to read: "In such cases, the rules of § 97.85(e) (1), (2) and (3) apply." A new paragraph (d) would be added to Section 97.87 to read, as follows:

. . . .

(d) Beacons under automatic control transmitting below 432.08 MHz are restricted to the following emissions: N0N, A1A, F1B, and J2A.

7. Section 97.114 would be amended by adding a new paragraph (d) as follows:

§ 97.114 Limitations on third-party traffic.

. . . .

(d) Third-party traffic from any amateur radio station under automatic control.

[FR Doc. 85-9246 Filed 4-16-85; 8:45 am]

BILLING CODE 6712-01-M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

49 CFR Part 393

[BMCS Docket No. MC-112; Notice No. 85-5]

Citizen Band Radios on Buses

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Withdrawal of advance notice of proposed rulemaking.

SUMMARY: The FHWA is withdrawing the advance notice of proposed rulemaking concerning the use of citizen band radios on buses. This action is being taken for lack of data or evidence to support further rulemaking. There were no adverse comments submitted to the docket against the recommendation of the National Academy of Sciences (NAS) that the DOT retain the status quo and allow motor carriers of passengers to continue to decide whether their drivers should be permitted to use CB's in buses, subject to collective bargaining.

FOR FURTHER INFORMATION CONTACT: Mr. Neill L. Thomas, Bureau of Motor Carrier Safety, (202) 755-1011; or Mrs. Kathleen S. Markman, Office of the Chief Counsel, (202) 426-0346, Federal Highway Administration, Department of Transportation, 400 Seventh St., SW., Washington, D.C. 20590. Office hours are from 7:45 a.m. to 4:15 p.m. ET, Monday through Friday.

SUPPLEMENTARY INFORMATION: A study of the use of CB's on buses was undertaken by the NAS as directed by Congress in the Bus Regulatory Reform Act of 1982 (Pub. L. 97-261, 96 Stat. 1120). In addition, the Secretary of Transportation was directed to initiate rulemaking to determine whether bus drivers should be permitted to use CB's on such vehicles. An advance notice of proposed rulemaking (ANPRM) was published in the **Federal Register**, January 11, 1985 (50 FR 1603) requesting comments on a recommendation by the NAS that the DOT retain the status quo and allow motor carriers of passengers to continue to decide whether their drivers should be permitted to use CB's in buses, subject to collective bargaining.

The NAS, in its report prepared by its Transportation Research Board (TRB),

entitled "Study of Safety Benefits and Costs of Using Citizen Band Radios on Intercity Buses", recommended that the Federal policy remain unchanged, and that individual companies determine for themselves whether or not to permit their drivers to use CB radios while on the job.

There were six comments submitted in response to the ANPRM. All six comments supported the recommendation of the TRB. In brief, the TRB concluded that the use of CB radios on intercity buses does not appear to encourage speeding, does not appear either to distract or stimulate drivers, nor does it appear to cause annoyance to passengers. Neither is there evidence of a significant number of on-board or external incidents or accidents, the effects of which might have been ameliorated by the use of a CB. Therefore, while CB's on intercity buses do not appear to do any harm, neither do they appear to make a meaningful contribution to the health, safety, and convenience of the intercity bus riding public.

Background

In response to a petition for rulemaking and to a number of inquiries concerning the action certain for-hire motor carriers of passengers had taken

to prohibit the use of CB radios on intercity buses, two public hearings were conducted jointly by the FHWA and the National Highway Traffic Safety Administration during April 1979. Meaningful evidence that CB radios have a direct effect on the safety of operation of motor vehicle did not surface from the data submitted at the hearings.

A Federal policy had previously been adopted by the Department of Transportation, the Interstate Commerce Commission and the Federal Communications Commission. The agencies involved stated that CB radios can offer a significant contribution to safety and service on the highways and their use was encouraged to promote highway safety and service.

The FHWA issued a Notice of Policy Statement on the Use of Citizen Band Radios (45 FR 3419, January 17, 1980) encouraging use of CB's because as an in-vehicle communication system, it can offer a significant contribution to safety and emergency service on the highways.

Congress instructed the Secretary of Transportation to give substantial weight to the recommendations and conclusions of the NAS. There were no adverse comments submitted to the docket. All six comments received supported the recommendation of the

NAS. The ANPRM clearly stated that the FHWA would continue to support its current policy unless comments to the docket contained meaningful evidence that indicated CB radios have a direct and positive effect on the safety of operation of motor passenger vehicles that would warrant further rulemaking. No such data was submitted. Therefore, this rulemaking is hereby withdrawn.

The FHWA has determined that this document contains neither a major proposal under Executive Order 12291 nor a significant proposal under the regulatory policies and procedures of the Department of Transportation. A draft regulatory evaluation has been prepared and is available in the public docket for review.

This action will not have a significant economic impact on small entities.

List of Subjects in 49 CFR Part 393

Highways and roads, Motor carriers, Motor vehicle equipment, Motor vehicle safety.

(49 U.S.C. 3102; 49 CFR 1.48)

(Catalog of Federal Domestic Assistance Program number 20.217, Motor Carrier Safety)

Issued on: April 9, 1985.

Kenneth L. Pierson,

Director, Bureau of Motor Carrier Safety.

[FR Doc. 85-9290 Filed 4-16-85; 8:45 am]

BILLING CODE 4910-22-M

Notices

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Committee on Governmental Processes and Governmental Tort Claims; Public Meetings

Committee on Governmental Processes

Date: Friday, May 3, 1985. Time: 9:30 AM. Location: Main Conference Room (11th floor), Covington & Burling, 1201 Pennsylvania Avenue, N.W., Washington, D.C. Agenda: Research projects before the committee. Proposed recommendation and draft report by Professors Barry B. Boyer and Errol E. Meidinger, concerning lawsuits brought by citizens under the federal environmental laws. Contact: David M. Pritzker, 202-254-7065.

Committee on Governmental Tort Claims

Date: Friday, April 26, 1985. Time: 10:00 AM. Location: 2120 L Street, N.W., Suite 500, Washington, D.C. Agenda: Organizational meeting of the ad hoc Committee on Governmental Tort Claims, which is charged with seeking implementation of prior Administrative Conference recommendations in the area and developing recommendations for further Conference research, statutory change, agency reform, or other action leading to a rationalization of the current system. Contact: Charles Pou, Jr., 202-254-7065.

Public Participation

Attendance at the committee meetings is open to the public, but limited to the space available. Persons wishing to attend should notify the contact person at least two days in advance of the meeting. The committee chairman may permit members of the public to present appropriate oral statements at the meeting. Any member of the public may file a written statement with a committee before, during, or after the meeting. Minutes of the meetings will be

available on request to the contact persons. The contact persons' mailing address is: Administrative Conference of the United States, 2120 L Street, NW, Suite 500, Washington, D.C. 20037. These meetings are subject to the Federal Advisory Committee Act (Pub. L. 92-463).

Richard K. Berg,
General Counsel.

April 15, 1985.

[FR Doc. 85-9311 Filed 4-16-85; 8:45 am]

BILLING CODE 6110-01-M

DEPARTMENT OF AGRICULTURE

Office of the Secretary

National Agricultural Research and Extension Users Advisory Board; Meeting

According to the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463, 86 Stat. 770-776), the Office of Grants and Program Systems announces the following meeting:

Name: National Agricultural Research and Extension Users Advisory Board.

Date: May 6-8, 1985.

Time: 8:30 a.m.-11:30 a.m., May 6-8, 1985.

Place:

Forest Products Laboratory (May 6, 1985), North Walnut Street, Madison, Wisconsin Wisconsin Center (May 7, 1985), University of Wisconsin, 702 Langdon, Madison, Wisconsin

The Edgewater (May 8, 1985), Lake Mendota at Wisconsin Avenue, Madison, Wisconsin

Type of Meeting: Open to the public.

Persons may participate in the meeting as time and space permit.

Comments: The public may file written comments before or after the meeting with the contact person below.

Purpose: The Board will be preparing a report to the Secretary of Agriculture assessing agricultural research and extension on policies, priorities, and programs.

Contact Person for Agenda and More Information: Marshall Tarkington, National Agricultural Research and Extension Users Advisory Board; Room 319-A, Administration Building, U.S. Department of Agriculture, Washington, DC 20250; telephone (202) 447-3684.

Done in Washington, DC, this 10th day of April 1985.

Marshall Tarkington,
Acting Executive Secretary.

[FR Doc. 85-9291 Filed 4-16-85; 8:45am]

BILLING CODE 3410-MT-M

Federal Register

Vol. 50, No. 74

Wednesday, April 17, 1985

Commodity Credit Corporation

1985 Tobacco Price Support Levels

AGENCY: Commodity Credit Corporation (CCC), USDA.

ACTION: Notice of Proposed Determination of 1985 Tobacco Price Support Levels.

SUMMARY: The purpose of this Notice of Proposed Determination is to request comments with respect to levels of price support for all eligible kinds of tobacco (except flue-cured) for the 1985 marketing year. The levels of price support for these kinds of tobacco are required to be determined under the provisions of section 106 of the Agricultural Act of 1949, as amended.

DATE: Comments must be received on or before May 17, 1985, to be assured of consideration.

ADDRESS: Written comments should be sent to the Director, Commodity Analysis Division, ASCS, U.S. Department of Agriculture, P.O. Box 2415, Washington, D.C. 20013. All written submissions made pursuant to this notice will be made available for public inspection from 8:15 a.m. to 4:45 p.m. Monday through Friday, in Room 3741, USDA South Building, 14th and Independence Avenue, S.W., Washington, D.C.

FOR FURTHER INFORMATION CONTACT

Robert H. Miller, (202) 447-8839 or Robert Tarczy, (202) 447-5187. A Preliminary Regulatory Impact Analysis describing the options considered in developing this notice and the impact of implementing each option is available on request from Mr. Tarczy.

SUPPLEMENTARY INFORMATION: This notice has been reviewed under USDA procedures established in accordance with Executive Order 12291 and Departmental Regulation 1512-1, and has been classified as "not major." The provisions of this notice will not result in: (1) An annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State or local governments, or geographical regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, the environment, or the ability of United States-based enterprises to compete with foreign-

based enterprises in domestic or export markets.

The title and number of the Federal Assistance Program to which this notice applies are: Title—Commodity Loans and Purchases; Number—10.051, as set forth in the Catalog of Federal Domestic Assistance.

It has been determined that the Regulatory Flexibility Act is not applicable to this notice since the Commodity Credit Corporation (CCC) is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject of this notice.

This program/activity is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR Part 3015, Subpart V, published at 48 FR 29115 (June 24, 1983). It has been determined by an environmental evaluation that this action will have no significant impact on the quality of the human environment. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

Since producers are making plans to plant their crops and must be aware of these determinations as soon as possible, the comment period is limited to 30 days.

Determination of Price Support

Price support is required to be made available for each crop of a kind of tobacco for which quotas are in effect or for which marketing quotas have not been disapproved by producers at a level which is determined in accordance with a formula prescribed in section 106 of the Agricultural Act of 1949, as amended (the "Act"). With respect to the 1985 crop of burley tobacco, the level of support is determined in accordance with sections 106 (b), (d), and (f) of the Act. With respect to the 1985 crop of other kinds of tobacco, except flue-cured and burley tobacco, the respective level of support is determined in accordance with section 106(b) of the Act.

Burley Tobacco

Section 106(f)(4) of Act provides that the level of support for the 1985 crop of burley tobacco shall be the level in cents per pound at which the 1984 crop of burley tobacco was supported, plus or minus, respectively, the amount by which (A) the support level for the 1985 crop, as determined under section 106(b) of the Act, is greater or less than (B) the support level for the 1984 crop, as determined under section 106(b) of the Act, as that difference may be adjusted

by the Secretary under section 106(d) of the Act if the support level under clause (A) is greater than the support level under clause (B). Accordingly, under section 106(f)(4) of the Act, the support level for the 1985 crop of burley tobacco will be the 1984 level, adjusted by the difference between (plus or minus) the 1985 "basic support level" and the 1984 "basic support level".

Section 106(b) of the Act provides that the "basic support level" for any year is determined by multiplying the support level for the 1959 crop of burley tobacco (57.2 cents per pound) by the ratio of the average of the index of prices paid by farmers including wage rates, interest, and taxes (referred to as the "parity index") for the three previous calendar years to the average index of such prices paid by farmers, including wage rates, interest, and taxes for the 1959 calendar year (298). For the 1985-crop year, the average parity indexes for the three previous years are: 1982—1076; 1983—1104; and 1984—1130. The average of the parity indexes for these years is 1103 and the ratio of the 1982-84 index to the 1959 index is 3.70. Accordingly, the "basic support level" for 1985 burley tobacco equals 211.6 cents per pound. For the 1984-crop year, the average parity indexes used to calculate the 1984 "basic support level" were: 1981—1035; 1982—1076; 1983—1105. The ratio of the 1981-83 index to the 1959 index equaled 3.60. Thus, the "basic support level" for the 1984 crop of burley tobacco equaled 205.9 cents per pound. The difference between the "basic support levels" for the 1984 and 1985 crops of burley tobacco is 5.7 cents per pound.

Section 106(d) of the Act provides that the Secretary of Agriculture may reduce the level of support which would otherwise be established for any grade of burley tobacco which the Secretary determines will likely be in excess supply. In addition, the weighted average of the level of support for all eligible grades of such tobacco must, after such reduction, reflect not less than 65 percent of the increase in the support level for such kind of tobacco which would otherwise be established under section 106 of the Act if the support level is higher than the support level for the preceding crop. Before any such reduction is made, the Secretary must consult with the associations handling price support loans and consideration must be given to the supply and anticipated demand of such tobacco, including the effect of such reduction on other kinds of quota tobacco. In determining whether the supply of any grade of any kind of tobacco of a crop will be excessive, the

Secretary shall take into consideration the domestic supply, including domestic inventories, the amount of such tobacco pledged as security for price support loans, and anticipated domestic and export demand, based on the maturity, uniformity and stalk position of such tobacco.

Supplies of burley tobacco are excessive (491 million pounds above the reserve supply level). In addition, by the end of the 1984 marketing year the two associations handling burley tobacco through which price support loans are made available to producers will hold an estimated 500 million pounds of burley tobacco which has been pledged as collateral for CCC price support loans. This loan inventory consists of almost all grades of burley tobacco. This inventory is equal to almost an entire season's use of burley tobacco.

Accordingly, it is proposed that the 1985 price support level for burley tobacco be 178.8 cents per pound. This is an increase of 3.7 cents per pound from the 1984 support level of 175.1 cents per pound, or 65 percent of the increase that otherwise would be established (5.7 cents).

Other Kinds of Tobacco

Section 106(f)(3) of the Act provides that for the 1985 crop of any kind of tobacco (other than burley and flue-cured tobacco) for which marketing quotas are in effect or for which marketing quotas are not disapproved by producers, the Secretary of Agriculture shall establish the support price at such level as will not narrow the normal price support differential between flue-cured tobacco and such other kind of tobacco. In establishing the support level under section 106(f)(3) for any such kind of tobacco, the Secretary shall take into consideration the cost of producing such kind of tobacco, the supply and demand conditions of such kind of tobacco, the comments received in response to this notice of proposed determinations, and such other relevant factors as the Secretary determines appropriate. In accordance with section 106(f)(2), the Secretary determined on February 28, 1985 that the support level for the 1985 crop of flue-cured tobacco would be 169.9 cents per pound, the same support level which was established for the 1984 crop of flue-cured tobacco. Accordingly, the support level for these other kinds of tobacco may not be increased from the 1984 support levels but may be decreased.

The levels of price support for the 1984 crops of the various kinds of tobacco, which were determined in

accordance with Sections 106(f) of the 1949 Act, are as follows:

Kind and type	Support (cents per pound)
Virginia fire-cured, type 21	118.8
KY-TN fire-cured, types 22-23	123.0
Dark air-cured, types 35-36	105.7
Virginia sun-cured, type 37	109.4
Cigar-filler and binder, types 42-44, 53-55	90.7
Puerto Rican, type 46	74.0

As noted in the following table, the supplies of all these kinds of tobacco for which price support is made available are currently at, or in excess of, the supply deemed adequate to meet domestic use and export needs. As a result of these increased supplies of tobacco, the quantity of tobacco pledged as collateral for CCC price support loans has also become excessive.

Kind and type	1984/85 production	1984/85 total supply	1984/85 reserve supply level	CCC loan collateral	1984/85 CCC loans as percent of production
Million pounds					
Virginia fire-cured, type 21	5.8	13.8	12.8	1.3	22.4
Kentucky-Tennessee fire-cured, types 22-23	47.8	112.0	102.2	11.7	24.5
Dark air-cured, types 35-36	17.5	60.2	55.1	6.7	38.3
Virginia sun-cured, type 37	.6	2.0	2.0	.3	50.0
Cigar-filler and binder, types 42-44, 53-55	17.7	82.1	75.6	.5	2.8
Puerto Rican, type 46	.8	6.9	3.6	.8	100.0

* Three times annual disappearance past 3 marketing years.

Because of the oversupply situation for fire-cured (type 21), fire-cured (types 22-23), dark air-cured, Virginia sun-cured, Puerto Rican filler, and cigar-filler and binder (types 42-44; 53-55), a range of respective 1985 price support levels is proposed consisting of a maximum level of support equal to the 1984 level of support and a minimum level of support which is 20 percent less than the 1984 level of support.

Proposed Determinations

Accordingly, the Secretary of Agriculture proposes to determine and announce 1985-crop price support levels for the following kinds of tobacco at the level or within the ranges set forth below:

Kind and type	Range (cents per pound)
Burley	178.8
Virginia fire-cured, type 21	95.0-118.8
KY-TN fire-cured, types 22-23	98.0-123.0
Dark air-cured, types 35-36	84.0-105.7
Virginia sun-cured, type 37	87.0-109.4
Cigar-filler and binder, types 42-44, 53-55	72.0-90.7
Puerto Rican filler (type 46)	60.0-74.0

Comments are requested with respect to the appropriate level of price support for such kinds of tobacco.

Authority: Secs. 4 and 5, 62 Stat. 1070, as amended, 1072, as amended, 15 U.S.C. 714b, 714c; Secs. 101, 106, 401, 403, 406, 63 Stat. 1051, as amended, 74 Stat. 6, as amended, 63 Stat. 1054, as amended, 1055, 7 U.S.C. 1441, 1445, 1421, 1423, 1426.

Signed at Washington, D.C., on April 12, 1985.

Milton J. Hertz,

Acting Executive Vice President, Commodity Credit Corporation.

[FR Doc. 85-8292 Filed 4-16-85; 8:45 am]

BILLING CODE 3410-05-M

1985 Tobacco Price Support Level (Flue-Cured)

AGENCY: Commodity Credit Corporation (CCC).

ACTION: Notice of Determination of 1985 Price Support Level for Flue-cured Tobacco.

SUMMARY: The purpose of this notice is to affirm the determination made by the Secretary of Agriculture for the 1985 crop of flue-cured tobacco in accordance with the Agricultural Act of 1949, as amended. The level of price support for flue-cured tobacco is required to be determined under the provisions of section 106 of the Agricultural Act of 1949, as amended. On February 28, 1985, the Secretary of Agriculture determined that the 1985-86 average support level for flue-cured tobacco shall be 169.9 cents per pound.

EFFECTIVE DATE: February 28, 1985.

FOR FURTHER INFORMATION CONTACT: Robert H. Miller, (202) 447-8839 or Robert Tarczy, (202) 447-5187. A Regulatory Impact Analysis describing the impacts of this notice is included in

the Preliminary Regulatory Impact Analysis of the 1985 crop support levels for tobacco and is available on request from Mr. Tarczy.

SUPPLEMENTARY INFORMATION: This notice has been reviewed under USDA procedures established in accordance with Executive Order 12291 and Departmental Regulation 1512-1, and has been classified as "not major." The provisions of this notice will not result in: (1) An annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State or local governments, or geographical regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, the environment, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The title and number of the Federal Assistance Program to which this notice applies are: Title—Commodity Loans and Purchases; Number—10.051, as set forth in the Catalog of Federal Domestic Assistance.

It has been determined that the Regulatory Flexibility Act is not applicable to this notice since the Commodity Credit Corporation (CCC) is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject of this notice.

This program/activity is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the notice related to 7 CFR Part 3015, Subpart V, published at 48 FR 29115 (June 24, 1983).

It has been determined by an environmental evaluation that this action will have no significant impact on the quality of the human environment. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

Determination of Price Support

Price support is required to be made available for each crop of a kind of tobacco for which quotas are in effect or for which marketing quotas have not been disapproved by producers at a level which is determined in accordance with a formula prescribed in section 106 of the Agricultural Act of 1949, as amended (the "Act").

Section 106(b) of the Act provides that the "basic support level" for any crop of a kind of tobacco for which marketing quotas are in effect shall be determined

by multiplying the support level for the 1959 crop tobacco by the ratio of the average of the index of prices paid by farmers including wage rates, interest, and taxes (parity index) for the three previous calendar years to the average index for 1959 (298). For the 1985-crop year, the average parity indexes for the three previous years are: 1982—1076; 1983—1104; and 1984—1130, making the 3-year average 1103. This ratio multiplied by the 1959 support level (55.5 cents per pound) results in the "basic support level" for 1985 flue-cured tobacco of 205.4 cents per pound. For the 1984 crop year calculation, the average parity indexes were: 1981—1035; 1982—1076; 1983—1105, making the average of 1072 and the ratio of the 1981-83 index to the 1959 index 3.60. That ratio (3.60) multiplied by the 1959 support (55.5 cents) results in the "basic support level" for the 1984 crop of 199.8 cents per pound. Thus, the 1985 "basic support level" is 2.8 percent above the 1984 level.

Section 106(f)(2) of the Act provides that the support level for the 1985 crop shall be the level in cents per pound at which the 1982 crop was supported if the support level otherwise determined under section 106(b) of the Act for the 1985 crop would not be more than 5 percent greater than the support level determined under section 106(b) for the 1984 crop. Therefore, the 1985 support level must equal the 1982 support level, which was 169.9 cents per pound.

Determination

Accordingly, it has been determined that the level of price support for the 1985 crop of flue-cured tobacco is 169.9 cents per pound. The grade loan rates reflecting this level of price support for the 1985 crop of tobacco will be available at county Agricultural Stabilization and Conservation Service offices, producer associations, and the Tobacco and Peanuts Division, Agricultural Stabilization and Conservation Service, Washington, D.C.

Authority: Secs. 4 and 5, 62 Stat. 1070, as amended, 1072 (15 U.S.C. 714b, 714c); Secs. 101, 106, 401, 403, 406, 63 Stat. 1051 as amended, 74 Stat. 8, as amended, 63 Stat. 1054, as amended, 63 Stat. 1055, as amended (7 U.S.C. 1441, 1445, 1421, 1423, 1426).

Signed at Washington, D.C. on April 12, 1985.

Milton Hertz,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. 85-9293 Filed 4-16-85; 8:45 am]

BILLING CODE 3410-05-M

Food and Nutrition Service

Organization, Functions and Delegations of Authority

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice of Agency Organization, Functions, and Delegations of Authority.

SUMMARY: This notice sets forth the organization, functions, and delegations of authority for the Food and Nutrition Service (FNS).

SUPPLEMENTARY INFORMATION: FNS was established by the Secretary of Agriculture on August 8, 1969, pursuant to authority under Reorganization Plan No. 2 of 1953. Authority is delegated by the Secretary of Agriculture to the Assistant Secretary for Food and Consumer Services in 7 CFR 2.15, and from the Assistant Secretary to the Administrator, FNS in 7 CFR 2.93 to administer the various food and nutrition programs, including the Food Stamp Program, School Lunch Program, child nutrition programs and commodity distribution programs. This notice supersedes the notice of FNS Organization, Functions and Delegations of Authority published at 48 FR 24156 (1983).

Section 1. General

The principal office of FNS is located in Alexandria, Virginia. Program activity in the field is carried on through seven regional offices. In addition, there are a number of special purpose offices geographically located in the field, which perform food stamp compliance, appeals review and certain automated data processing services.

Section 2. Organization and Functions

(a) *The Administrator.* The Administrator reports to the Assistant Secretary for Food and Consumer Services. He/she serves as the chief executive officer of FNS and is responsible for the overall planning, direction and control of FNS programs and activities. He/she must establish and maintain working relationships and lines of communication with the Secretary and Deputy Secretary of Agriculture, Assistant Secretary, Congress, heads of other operating administrations, other agencies and the general public.

(b) *Associate Administrator.* The Associate Administrator reports to the Administrator and shares with the Administrator responsibility for the overall development, administration and coordination of FNS activities, providing executive leadership in developing, administering, executing and

coordinating operational programs of the Agency; reviewing proposed programs, policies, and procedures inherent in Agency operations to determine that they are coordinated internally with other agencies of the Department, Federal, State and local government, or cooperating agencies; and providing liaison with General Accounting Office (GAO) and coordinating GAC activities within FNS.

(c) *Director, Office of Analysis and Evaluation.* The Director, Office of Analysis and Evaluation, provides to the Administrator valid and timely analysis and evaluation information to support decisions regarding the legislative, budgetary, regulatory and program management processes.

(d) *Director, Office of Government Affairs and Public Information.* The Director, Office of Governmental Affairs and Public Information, establishes clear and continuing lines of communication between Congress and FNS, prepares legislative reports, monitors and reports on legislation status and other appearances before legislators and their staffs. He/she is responsible for the planning, development, coordination and implementation of information programs in support of FNS' policies and programs.

(e) *Deputy Administrator for Family Nutrition Programs.* The Deputy Administrator for Family Nutrition Programs provides direction and leadership in the formulation of Food Stamp policies and requirements, and in the development of program regulations and directives, the oversight of food assistance program grants and the review and evaluation of FNS Regional Offices' and States' efforts to implement Food Stamp Program regulations, policies and requirements.

(f) *Deputy Administrator for Special Nutrition Programs.* The Deputy Administrator for Special Nutrition Programs participates with the Administrator in the overall planning and formulation of all special nutrition policies, programs and activities of FNS and provides direction and leadership in the administration of Special Nutrition Programs.

(g) *Regional Administrators.* The Regional Administrators are responsible for administering the Food Stamp and Special Nutrition Programs including Child Nutrition, Special Supplemental Food and Food Distribution within the geographical boundaries of assigned region activities. The United States and its territories are divided into the following seven regions:

(1) Mid-Atlantic Regional Office: Pennsylvania, New Jersey, Delaware, Maryland, West Virginia, Virginia, Puerto Rico, and the Virgin Islands.

(ii) Midwest Regional Office: Minnesota, Wisconsin, Michigan, Illinois, Indiana, and Ohio.

(iii) Mountain Plains Regional Office: Montana, Wyoming, North Dakota, South Dakota, Nebraska, Iowa, Utah, Colorado, Kansas, and Missouri.

(iv) Northeast Regional Office: Maine, Vermont, New Hampshire, Massachusetts, Rhode Island, Connecticut, and New York.

(v) Southeast Regional Office: Tennessee, Mississippi, Alabama, Georgia, North Carolina, South Carolina and Florida.

(vi) Southwest Regional Office: Texas, Oklahoma, Arkansas, and Louisiana.

(vii) Western Regional Office: Washington, Oregon, Idaho, California, Nevada, Arizona, Alaska, Hawaii, American Samoa, and Northern Marianas.

(h) *Director, Office of Regional Operations.* The Director, Office of Regional Operations, provides staff assistance to the Administrator to assure uniformity, consistency and timeliness in the development and conveyance of FNS policy which affects the operation of Regional offices, and provides leadership for administrative reviews of certain Agency actions appealed by program cooperators.

(i) *Deputy Administrator for Financial Management.* Deputy Administrator for Financial Management participates with the Administrator in the overall planning and formulation of all financial policies, programs and activities of FNS and directs and administers the Agency's financial management program through the development, maintenance and operation of comprehensive systems that meet management needs.

(j) *Deputy Administrator for Management.* The Deputy Administrator for Management is responsible for participating with the Administrator in the overall planning, formulation, and direction of all administrative management policies and program activities of FNS, and providing executive direction to FNS administrative management activities and operation.

Section 3. Delegations of Authority

(a) *Associate Administrator.* The Associate Administrator is hereby delegated the authority to perform all the duties and to exercise all the functions and powers which are now or which may hereafter be vested in the Administrator, except such authority as

is, or may be, reserved to the Administrator.

(b) *Deputy and Regional Administrators.* In carrying out their responsibilities, the Deputy Administrators for Family Nutrition Programs, Special Nutrition Programs, Financial Management, and Management, and Regional Administrators are hereby delegated authority to perform all the duties and to exercise all the functions and powers which are now or which may hereafter be vested in the Administrator (including the power of redelegation except when prohibited) except may hereafter be vested in the Administrator (including the power of redelegation except when prohibited) except such authority as is or may be reserved to the Administrator. Each Deputy and Regional Administrator shall be primarily responsible for the program and activities of FNS assigned them.

(c) *Concurrent Authority and Responsibility.* No delegation or authorization prescribed herein shall preclude the Administrator, the Associate Administrator, each Deputy Administrator, or Regional Administrator from exercising any of the powers of functions or from performing any of the duties conferred herein, and any such delegation or authorization is subject at all times to withdrawal or amendment by the Administrator and, in their respective fields, each Deputy Administrator or Regional Administrator. The officers to whom authority is delegated herein shall maintain close working relationships with the officers to whom they report, keep them advised with respect to major problems and developments especially major policy questions or other important considerations or questions including matters involving relationships with other Federal agencies, other agencies of the Department, other divisions or offices of FNS or other governmental or private organizations or groups.

(d) *Authority to Act as Administrator.* In the Administrator's absence the person designated by the Administrator or Acting Administrator as Acting Administrator is hereby delegated authority to perform all duties and to exercise all the functions and powers which are now or which hereafter may be vested in the Administrator.

(e) *Prior Authorizations and Delegations.* All prior delegations and redelegations of authority relating to any functions, program or activity covered by this Statement of Organization, Functions and Delegations of Authority, shall remain in effect except as they are inconsistent herewith

or are hereafter amended or revoked. Nothing herein shall affect the validity of any action heretofore taken under prior delegations or redelegations of authority or assignments of functions.

Dated March 18, 1985.

Robert E. Leard,

Administrator.

[FR Doc. 85-9217 Filed 4-16-85; 8:45 am]
BILLING CODE 3410-30-M

Forest Service

Coronado National Forest Grazing Advisory Board; Meeting

The Coronado National Forest Grazing Advisory Board will meet at 10 a.m., Room 4B, May 21, 1985, at the Federal Building, 301 West Congress, Tucson, Arizona. The purpose of this meeting is to discuss allotment management planning and the use of range betterment funds.

The meeting will be open to the public. Persons who wish to attend should notify Larry Allen, Coronado Supervisor's Office, telephone 602-629-6418. Written statements will be filed with the board before or after the meeting.

The board has established the following rule for public participation: Nonmembers are asked to withhold comments until the close of business.

R.B. Tippeconic,
Forest Supervisor.

April 9, 1985.

[FR Doc. 85-9209 Filed 4-16-85; 8:45 am]
BILLING CODE 4310-84-M

DEPARTMENT OF COMMERCE

Agency Form Under Review by the Office of Management and Budget (OMB)

DOC has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: International Trade Administration

Title: Written Assurance for Exports of Technical Data Under General License

Form number: Agency—EAR 379.4(f); OMB—0625-014

Types of request: Extension of the expiration date of a currently approved collection

Burden: 250 respondents; 125 reporting hours

Needs and uses: Before certain technical data can be exported from the

U.S. under the General License for Technical Data (GTDR), the foreign importer must submit to the U.S. exporter a written assurance that he will not reexport directly or indirectly the technical data and/or product to specific countries. The purpose of the written assurance is to prevent technical data capable of producing strategic commodities from being shipped to Soviet Bloc countries.

Affected public: Businesses or other for-profit institutions, small businesses or organizations

Frequency: On occasion

Respondent's obligation: Required to obtain or retain a benefit

OMB desk officer: Sheri Fox, 395-3785.

Copies of the above information collection proposal can be obtained by calling or writing DOC Clearance Officer, Edward Michals (202) 377-4217, Department of Commerce, Room 6622, 14th and Constitution Avenue, N.W., Washington, D.C. 20230.

Written comments and recommendations for the proposed information collection should be sent to Sheri Fox, OMB Desk Officer, Room 3235, New Executive Office Building, Washington, D.C. 20503.

Dated: April 12, 1985.

Edward Michals,

Departmental Clearance Officer.

[FR Doc. 85-9219 Filed 4-16-85; 8:45]

BILLING CODE 3510-CW-M

Agency Form Under Review by the Office of Management and Budget (OMB)

DOC has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: NOAA

Title: Flood Damage Report

Form number: Agency—None; OMB—0648-0001

Type of Request: Reinstatement of a previously approved collection for which approval has expired.

Burden: 750 respondents; 4,500 reporting hours

Needs and uses: Information on specific flood events is to be obtained from Federal, state and local officials and selected private citizens to evaluate the effectiveness of forecast and warning services, to learn what actions agencies and citizens take in response to warnings, and to determine what improvements should be made.

Affected public: Individuals and households, Federal, state, and local governments, farms, businesses and

other for-profit non-profit institutions, and small businesses and organizations.

Frequency: On occasion

Respondent's obligation: Voluntary

OMB desk officer: Sheri Fox, 395-3785.

Copies of the above information collection proposal can be obtained by calling or writing DOC Clearance Officer, Edward Michals (202) 377-4217, Department of Commerce, Room 6622, 14th and Constitution Avenue, N.W., Washington, D.C. 20230.

Written comments and recommendations for the proposed information collection should be sent to Sheri Fox, OMB Desk Officer, Room 3235, New Executive Office Building, Washington, D.C. 20503.

Dated: April 11, 1985.

Edward Michals,

Departmental Clearance Officer.

[FR Doc. 85-9223 Filed 4-16-85; 8:45 am]

BILLING CODE 3510-CW-M

Office of the Secretary

Frequency Management Advisory Council; Renewal

In accordance with the provisions of the Federal Advisory Committee Act, 5 U.S.C. App. 2 and General Services Administration (GSA) Interim Rule on Federal Advisory Committee Management, CFR Part 101-8, as amended, and after consultation with GSA, the Secretary of Commerce has determined that the renewal of the Frequency Management Advisory Council is in the public interest in connection with the performance of duties imposed on the Department by law.

The Council was first established on July 19, 1965, and was to terminate on April 11, 1985. It provided advice to the Director of the Office of Telecommunications Policy (OTP), Executive Office of the President, until that office was merged by Executive order 12048 of March 27, 1978, into the Department of Commerce, National Telecommunications and Information Administration.

In reviewing the need for the Council, the Secretary has reaffirmed its original purpose of providing advice on radio frequency spectrum allocation and assignment matters and means by which the effectiveness of Federal Government frequency management may be enhanced. Research indicates that the Council's function cannot be accomplished by any organizational element or other committee of the Department.

The Council shall continue with a balanced representation of 15 members, chaired by the Assistant Secretary for Communications and Information or designee, and will operate in compliance with the provisions of the Federal Advisory Committee Act.

Copies of the Council's revised Charter will be filed with appropriate committees of Congress and with the Library of Congress.

Inquiries or comments may be addressed to the Committee Control Officer, Mr. Charles L. Hutchison, National Telecommunications and Information Administration, U.S. Department of Commerce, Room 4706, Washington, D.C. 20230, telephone: (202) 377-0805, or the Department Committee Management Analyst, telephone: (202) 377-4217.

Dated: April 9, 1985.

Katherine M. Bulow,

Assistant Secretary for Administration.

[FR Doc. 85-9221 Filed 4-16-85; 8:45 am]

BILLING CODE 3510-SS-M

Foreign-Trade Zones Board

[Order No. 298]

Approval for Expansion of Foreign-Trade Zone No. 50 at a Site in Ontario, CA, Adjacent to the Los Angeles-Long Beach Customs Port of Entry

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a-81u), and the Foreign-Trade Zones Board Regulations (15 CFR Part 400), the Foreign-Trade Zones Board (the Board) adopts the following order:

Whereas, the Board of Harbor Commissioners of the City of Long Beach, California, Grantee of Foreign-Trade Zone No. 50 in Long Beach, has applied to the Board for authority to expand its general-purpose zone to include an additional site in Ontario, California, adjacent to the Los Angeles-Long Beach Customs port of entry;

Whereas, the application was accepted for filing on August 24, 1984, and notice inviting public comment was given in the *Federal Register* on September 10, 1984 (Docket No. 37-84, 49 FR 35534);

Whereas, an examiners committee has investigated the application in accordance with the Board's regulations and recommends approval;

Whereas, the expansion is necessary to improve zone services in the Los Angeles area; and,

Whereas, the Board has found that the requirements of the Foreign-Trade

Zones Act, as amended, and the Board's regulations are satisfied, and that approval of the application is in the public interest;

Now, therefore, the Board hereby orders:

That the Grantee is authorized to expand its zone in accordance with the application filed August 24, 1984. The Grantee shall notify the Executive Secretary of the Board for approval prior to the commencement of any manufacturing operations. The authority given in this Order is subject to settlement locally by the District Director of Customs and the District Army Engineer regarding compliance with their respective requirements relating to foreign-trade zones.

Signed at Washington, D.C., this 2nd day of April 1985.

William T. Archey,

Acting Assistant Secretary of Commerce for Trade Administration; Chairman, Committee of Alternates, Foreign-Trade Zones Board.

Attest:

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 85-9277 Filed 4-16-85; 8:45 am]

BILLING CODE 3510-05-M

[Order No. 292]

Approval for Expansion of Foreign-Trade Zone No. 86, Tacoma, WA

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a-81u), and the Foreign-Trade Zones Board Regulations (15 CFR Part 400), the Foreign-Trade Zones Board (the Board) adopts the following order:

Whereas, the Puget Sound Foreign-Trade Zone Association, Grantee of Foreign-Trade Zone No. 86, has applied to the Board for authority to expand its general-purpose zone to include additional acreage within the Port of Tacoma Customs port of entry;

Whereas, the application was accepted for filing on September 10, 1984, and notice inviting public comment was given in the *Federal Register* on September 21, 1984 (Docket No. 43-84, 49 FR 37132);

Whereas, an examiners committee has investigated the application in accordance with the Board's regulations and recommends approval;

Whereas, the expansion is necessary to improve zone services in the Tacoma area; and,

Whereas, the Board has found that the requirements of the Foreign-Trade Zones Act, as amended, and the Board's regulations are satisfied, and that

approval of the application is in the public interest;

Now, therefore, the Board hereby orders:

That the Grantee is authorized to expand its zone in accordance with the application filed September 10, 1984. The Grantee shall notify the Executive Secretary of the Board for approval prior to the commencement of any manufacturing operations. The authority given in this Order is subject to settlement locally by the District Director of Customs and the District Army Engineer regarding compliance with their respective requirements relating to foreign-trade zones.

Signed at Washington, D.C., this 3rd day of April 1985.

William T. Archey,

Acting Assistant Secretary of Commerce for Trade Administration; Chairman, Committee of Alternates, Foreign-Trade Zones Board.

Attest:

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 85-9278 Filed 4-16-85; 8:45 am]

BILLING CODE 3510-05-M

[Order No. 293]

Approval for Relocation of Foreign-Trade Zone No. 18, San Jose, CA

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a-81u), and the Foreign-Trade Zones Board Regulations (15 CFR Part 400), the Foreign-Trade Zones Board (the Board) adopts the following order:

Whereas, the City of San Jose, California, Grantee of Foreign-Trade Zone No. 18, has applied to the Board for authority to relocate its general-purpose zone to a larger site on Cinnabar Street in San Jose, within the San Francisco-Oakland Customs port of entry;

Whereas, the application was accepted for filing on October 29, 1984, and notice inviting public comment was given in the *Federal Register* on November 8, 1984 (Docket No. 46-84, 49 FR 44659);

Whereas, an examiners committee has investigated the application in accordance with the Board's regulations and recommends approval;

Whereas, the relocation is necessary to improve zone services in the San Jose area; and,

Whereas, the Board has found that the requirements of the Foreign-Trade Zones Act, as amended, and the Board's regulations are satisfied, and that approval of the application is in the public interest;

Now, Therefore, the Board hereby orders:

That the Grantee is authorized to relocate its zone in accordance with the application filed October 29, 1984. The Grantee shall notify the Executive Secretary of the Board for approval prior to the commencement of any manufacturing operations. The authority given in this Order is subject to settlement locally by the District Director of Customs and the District Army Engineer regarding compliance with their respective requirements relating to foreign-trade zones.

Signed at Washington, D.C., this 3rd day of April 1985.

William T. Archey,

Acting Assistant Secretary of Commerce for Trade Administration; Chairman, Committee of Alternates, Foreign-Trade Zones Board.

Attest:

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 85-9279 Filed 4-16-85; 8:45 am]

BILLING CODE 3510-05-M

International Trade Administration

[Case No. 663]

Josef Forstner, Forson Elektronische Geraete GmbH; Order Denying Export Privileges

The U.S. Department of Commerce (Department), pursuant to the provisions of § 387.8(c) of the Export Administration Regulations (15 CFR Parts 368-399 (1984)) (Regulations), has petitioned the Hearing Commissioner for an order denying all export privileges to Josef Forstner (Forstner), individually and doing business as Forson Elektronische Geraete GmbH (Forson) Forson Elektronische Geraete GmbH; Breitenfurterstrasse 183, A-1120 Vienna, Austria.

The Department states that Forstner and Forson are under investigation by the Department's Office of Export Enforcement (OEE). During the course of OEE's investigation, Forson, on or about June 5, 1984, denied permission for an on-site post-shipment inspection. Forstner subsequently acknowledged receipt of certain U.S.-origin equipment; however, he refused to state its location. By letter of December 13, 1984, which was personally served that day by the Department's representative in Vienna, OEE asked Forstner and Forson, in connection with a post-shipment check and pursuant to § 387.8 of the Regulations, to answer written interrogatories and to produce records in their possession within 20 days of

receipt of the letter. To date, neither Forstner nor Forson has furnished answers to the interrogatories, produced the requested records, or given any reason for their failure to do so.

Based upon the showing made by the Department, I find: (i) That respondents have neither answered the interrogatories, produced the requested records, nor shown good cause for their continued failure to answer the interrogatories or to produce the requested records, and (ii) that an order denying all export privileges to Josef Forstner, individually and doing business as Forson Elektronische Geräte GmbH, is required in the public interest to facilitate enforcement of the Export Administration Act of 1979, as amended (50 U.S.C. app. 2401-2420 (1982)), and the Regulations.¹

Anyone who is now or may in the future be dealing with the respondents or anyone who is now or may be subsequently named as a related party in transactions that in any way involve U.S.-origin commodities or technical data is specifically alerted to the provisions set forth in Paragraph IV below.

Accordingly, it is hereby ordered.

I. All outstanding validated export licenses in which any respondent or any related party appears or participates, in any manner or capacity, are hereby revoked and shall be returned forthwith to the Office of Export Administration for cancellation.

II. The respondents, their successors or assignees, officers, partners, representatives, agents, and employees hereby are denied all privileges of participating, directly or indirectly, in any manner or capacity, in any transaction involving commodities or technical data exported or to be exported from the United States, in whole or in part, or that are otherwise subject to the Regulations. Without limiting the generality of the foregoing, participation prohibited in any such transaction, either in the United States or abroad, shall include participation, directly or indirectly, in any manner or capacity: (1) As a party or as a representative of a party to a validated export license application, (b) in preparing or filing any export license application, or reexport authorization, or any document to be submitted therewith, (c) in obtaining or using any

validated or general export license or other export control document, (d) in carrying on negotiations with respect to, or in receiving, ordering, buying, selling, delivering, storing, using, or disposing of, in whole or in part, any commodities or technical data exported from the United States, or to be exported, and (e) in financing, forwarding, transporting, or other servicing of such commodities or technical data. Such denial of export privileges shall extend only to those commodities and technical data which are subject to the Act and the Regulations.

III. Such denial of export privileges shall extend not only to the respondents, but also to their agents and employees and to any successors. After notice and opportunity for comment, such denial may also be made applicable to any person, firm, corporation, or business organization with which respondents are now or hereafter may be related by affiliation, ownership, control, position of responsibility, or other connection in the conduct of export trade or related services. One business organization now known to be related to Forstner and Forson through an affiliation in the conduct of trade, and which is accordingly subject to the provisions of this order, is:

Fuchs GmbH, Schoenbrunnerstrasse
237, A-1120, Vienna, Austria

IV. No person, firm, corporation, partnership or other business organization, whether in the United States or elsewhere, without prior disclosure to and specific authorization from the Office of Export Administration, shall, with respect to U.S.-origin commodities and technical data, do any of the following acts, directly or indirectly, or carry on negotiations with respect thereto, in any manner or capacity, on behalf of or in any association with any respondent or any related party, or whereby any respondent or any related party may obtain any benefit therefrom or have any interest or participation therein, directly or indirectly: (a) Apply for, obtain, transfer, or use any license, Shipper's Export Declaration, bill of lading, or other export control document relating to any export, reexport, transshipment, or diversion of any commodity or technical data exported in whole or in part, or to be exported by, to, or for any respondent or any related party denied export privileges; or (b) order, buy, receive, use, sell, deliver, store, dispose of, forward, transport, finance, or otherwise service or participate in any export, reexport, transshipment, or diversion of any

commodity or technical data exported or to be exported from the United States.

V. In accordance with the provisions of § 387.8(c) and § 388.19(b) of the Regulations, any respondent or any related party may, after answering the written interrogatories and producing the requested materials, or providing information that would constitute good cause for failure to do so, move at any time to vacate or modify this denial order by filing with the Hearing Commissioner, International Trade Administration, U.S. Department of Commerce, Room H6716, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230, an appropriate motion for relief and may also request an oral hearing thereon, which, if requested, shall be held before the Hearing Commissioner at the earliest convenient date.

VI. This Order is effective immediately. It remains in effect until respondents furnish responsive answers to the written interrogatories and produce the requested reports, or until they give adequate reason for their failure or refusal to do so, or until five years from the date of this Order, whichever occurs earlier. A copy of this Order and Parts 387 and 388 of the Regulations shall be served upon each respondent and related party.

Date: April 10, 1985.

Thomas W. Hoya,

Hearing Commissioner.

[FR Doc. 85-9220 Filed 4-16-85; 8:45 am]

BILLING CODE 3510-07-M

Management-Labor Textile Advisory Committee; Open Meeting

A meeting of the Management-Labor Textile Advisory Committee will be held Tuesday, May 7, 1985 at 1:00 p.m., Herbert C. Hoover Building, Room 6802, 14th Street and Constitution Avenue, NW., Washington, D.C. (The Committee was established by the Secretary of Commerce on October 18, 1961 to advise Department officials on problems and conditions in the textile and apparel industry).

Agenda: Review of import trends, implementation of textile agreements, report on conditions in the domestic market, and other business.

The meeting will be open to the public with a limited number of seats available. For further information or copies of the minutes contact Helen L. LeGrande (202) 377-3737.

¹ The authority granted by the Act terminated on March 30, 1984. The Regulations have been continued in effect by Executive Order 12470, 49 FR 12096, April 3, 1984, under the authority of the International Emergency Economic Powers Act (50 U.S.C. 1701-1706 (1982)).

Dated: April 10, 1985.

Walter C. Lenahan,

Deputy Assistant Secretary for Textiles and Apparel.

[FR Doc. 85-9225 Filed 4-16-85; 8:45 am]

BILLING CODE 3510-DR-M

Importers and Retailers' Textile Advisory Committee; Open Meeting

A meeting of the Importers and Retailers' Textile Advisory Committee will be held Wednesday, April 24, 1985 at 2:30 p.m., Herbert C. Hoover Building, Room 6802, 14th Street and Constitution Avenue, NW., Washington, D.C. (The Committee was established by the Secretary of Commerce on August 13, 1963 to advise Department officials of the effects on import markets of cotton, wool, and man-made fiber textile and apparel agreements).

Agenda: Review of import trends, implementation of textile agreements, report on conditions in the domestic market, and other business.

The meeting will be open to the public with a limited number of seats available. For further information or copies of the minutes contact Helen L. LeGrande (202) 377-3737.

Dated: April 10, 1985.

Walter C. Lenahan,

Deputy Assistant Secretary for Textiles and Apparel.

[FR Doc. 85-9226 Filed 4-16-85; 8:45 am]

BILLING CODE 3510-DR-M

[C-560-401, C-565-401 and C-489-401]

Termination of Countervailing Duty Investigations; Certain Textile Mill Products and Apparel From Indonesia, the Philippines, and Turkey

AGENCY: Import Administration, International Trade Administration, Commerce.

ACTION: Notice.

SUMMARY: On April 8, 1985, the petitioners withdrew their countervailing duty petitions on certain textile mill products and apparel from Indonesia, the Philippines and Turkey. Their letters of withdrawal appear as Appendix A to this notice. Based on the Withdrawals, we are terminating the countervailing duty investigations.

EFFECTIVE DATE: April 17, 1985.

FOR FURTHER INFORMATION CONTACT: Mary A. Martin, Office of Investigations, Import Administration, International Trade Administration, United States Department of Commerce, 14th Street & Constitution Avenue, NW., Washington, D.C. 20230; telephone (202) 377-3464.

SUPPLEMENTARY INFORMATION:

Petitions

We received petitions on July 20, 1984, concerning Indonesia and Turkey and on August 2, 1984, concerning the Philippines, from counsel for the American Textile Manufacturers Institute (ATMI), the Amalgamated Clothing and Textile Workers Union (ACTWU), and the International Ladies' Garment Workers Union (ILGWU), on behalf of the U.S. industries producing certain textiles and textile products. In compliance with the filing requirements of § 355.26 of the Commerce Regulations (19 CFR 355.26), the petitions alleged that manufacturer, producers, or exporters in Indonesia, Turkey, and the Philippines of certain textiles and textile products receive, directly or indirectly, benefits which constitute bounties or grants within the meaning of section 303 of the Traffic Act of 1930, as amended (the Act).

We found that the petitions contained sufficient grounds upon which to initiate countervailing duty investigations, and we initiated such investigations on Turkey and Indonesia on August 9, 1984, (49 FR 32641 and 32642) and on the Philippines on August 30, 1984, (49 FR 34381). We stated that we expected to issue preliminary determinations by October 15, 1984, on Turkey and Indonesia and by October 25, 1984, on the Philippines. On September 21, 1984, we determined these investigations to be "extraordinarily complicated," as defined in section 703(c)(1)(B) of the Act. Therefore, we extended the period for making our preliminary determinations by 65 days until December 17, 1984, for Indonesia and Turkey, and until December 31, 1984, for the Philippines (49 FR 40198).

On December 3, 1984, the petitioners amended their petitions to include the following ATMI member firms as individual petitioners with respect to textile mill products:

- Belton Industries, Inc., of Belton, S.C.;
- Burlington Industries, Inc., of Greensboro, N.C.;
- Chatham Manufacturing Company of Elkin, N.C.;
- Milliken & Company of Spartanburg, S.C.;
- Mount Vernon Mills, Inc., of Greensville, S.C.;
- Shuford Mills, Inc., of Hickory, N.C.;
- J.P. Stevens & Co., Inc., of New York, N.Y.; and
- West Point-Pepperell, Inc., of West Point, Ga.

On December 17, 1984, the Department determined that ATMI is not an "interested party" under section

771(9)(E) of the Act, and has no standing as a petitioner in these investigations. The Department accepted the amendment to add the eight firms listed above as petitioners with respect to textile mill products.

We issued our preliminary determinations that certain benefits which constitute bounties or grants within the meaning of the countervailing duty law are being provided to manufacturers, producers, or exporters of certain textile mill products and apparel from Indonesia and Turkey on December 17, 1984, and from the Philippines on December 31, 1984, (49 FR 49672; 49 FR 49661; and 50 FR 1607).

The Office of the U.S. Trade Representative announced on February 25, March 4, and March 15, 1985, that Turkey, Indonesia and the Philippines, respectively, are "countries under the Agreement" as set out in section 701(b) of the Act (50 FR 8428; 50 FR 9342; and 50 FR 11471). As a result, title VII of the Act became applicable to the countervailing duty investigations. According to section 102 of the Trade Agreements Act of 1979, once title VII becomes applicable any pending investigation under section 303 of the Act must terminate. Where a preliminary determination, but not a final determination, has been made under section 303, the case is to be treated as if the preliminary determination under section 703 was made the day title VII first applied to that country. Therefore, we terminated the investigations we initiated under section 303 of the Act and issued preliminary determinations under title VII of the Act (50 FR 9816; 50 FR 9861; 50 FR 11925).

On April 3, 1985, petitioners amended the petitions in these cases with respect to the description of the textile mill products by removing a number of *Tariff Schedules of the United States Annotated (TSUSA)* item numbers from the scope of the investigation.

Scope of the Investigations

The products covered by these investigations are certain textile mill products and apparel which are described in Appendices B, C and D attached to this notice.

Withdrawal of Petitions

On April 8, 1985, petitioners notified us that they were withdrawing their petitions. Under section 704(a)(1) of the Act (19 U.S.C. 1671c(a)(1)), upon withdrawal of a petition, the administering authority may terminate an investigation after giving notice to all parties to the investigation. We have

notified all parties to the investigation of petitioners' withdrawal and our intention to terminate and have consulted the International Trade Commission. Pursuant to § 355.30(a) of our regulations (19 CFR 355.30(a)), we have determined that termination of these cases is in the public interest.

For these reasons, we are terminating our investigations of certain textile mill products and apparel from Indonesia, the Philippines and Turkey.

Termination of Suspensions of Liquidation

Pursuant to section 705(c)(2) of the Act, the suspensions of liquidation of all entries entered, or withdrawn from warehouse, for consumption of certain textile mill products and apparel from Indonesia, the Philippines and Turkey effective December 17 and December 31, 1984, respectively, as directed in our notices of "Preliminary Affirmative Countervailing Duty Determinations: Certain Textile Mill Products and Apparel from Indonesia, the Philippines and Turkey" (49 FR 49672; 50 FR 1607 and 49 FR 49661) are hereby terminated. Any cash deposits on entries of certain textile mill products and apparel from Indonesia, the Philippines and Turkey pursuant to these suspensions of liquidation shall be refunded and any bonds shall be released.

Dated: April 11, 1985

C. Christopher Parlin,

Acting Deputy Assistant Secretary for Import Administration.

Appendix A

Wilmer, Cutler & Pickering,

1666 K Street, NW., Washington, D.C. 20006

April 8, 1985.

Inv. No. C-560-401

Total number of pages: 2

This document does not contain privileged, confidential or business proprietary information or information subject to administrative protective order

By Hand

Secretary

U.S. International Trade Commission, 701 E Street NW., Washington, D.C. 20436

Secretary of Commerce

Attention: Import Administration, Central Records Unit, Room B-099

Department of Commerce,

Pennsylvania Avenue at 14th Street, NW., Washington, D.C. 20230

Re: Textile Mill Products and Apparel From Indonesia

Gentlemen: Petitioners in the above-captioned investigation hereby withdraw their petition.

Very truly yours,

Deborah M. Levy.

Wilmer, Cutler & Pickering,

1666 K Street, NW., Washington, D.C. 20006

April 8, 1985.

Inv. No. C-565-401

Total number of pages: 2

This document does not contain privileged, confidential or business proprietary information or information subject to administrative protective order

By Hand

Secretary

U.S. International Trade Commission, 701 E Street NW., Washington, D.C. 20436

Secretary of Commerce

Attention: Import Administration, Central Records Unit, Room B-099

Department of Commerce,

Pennsylvania Avenue at 14th Street, NW., Washington, D.C. 20230

Re: Textile Mill Products and Apparel From The Philippines

Gentlemen: Petitioners in the above-captioned investigation hereby withdraw their petition.

Very truly yours,

Deborah M. Levy.

Wilmer, Cutler & Pickering.

1666 K Street, NW., Washington, D.C. 20006

April 8, 1985.

Inv. No. C-489-401

Total number of pages: 2

This document does not contain privileged, confidential or business proprietary information or information subject to administrative protective order

By Hand

Secretary

U.S. International Trade Commission, 701 E Street NW., Washington, D.C. 20436

Secretary of Commerce

Attention: Import Administration, Central Records Unit, Room B-099

Department of Commerce,

Pennsylvania Avenue at 14th Street, NW., Washington, D.C. 20230

Re: Textile Mill Products and Apparel From Turkey

Gentlemen: Petitioners in the above-captioned investigation hereby withdraw their petition.

Very truly yours,

Deborah M. Levy.

TURKEY—Appendix B

[The products covered by these investigations are certain textile mill products and apparel, which are currently classified under the item numbers of the Tariff Schedules of the United States, Annotated (TSUSA) listed below]

A. Textile Mill Products

Yarns

301.1100	301.2000	301.3000	301.4000	302.1022	302.1024	303.2042
307.6810	307.6830	307.6850	310.0214	310.4027	310.6045	310.6050
310.9000	310.9120					

Fabric

320.1019	320.1034	320.1045	320.1071	320.1077	321.4016	321.4023
321.4069	321.4073	322.2015	322.2017	322.2029	322.2036	322.2040
322.2047	322.2055	322.2056	322.2065	322.2070	322.2079	322.2097
336.6447	338.1574	338.1578				

Special construction Fabrics

346.6050

Textile Furnishings

360.4215	360.4815	360.4825	360.4855	360.8400	361.0510	361.2405
361.5000	360.7000	361.5630	361.5650	363.1040	363.2580	363.5130
363.6540	363.7500	364.1300	364.2300	365.7825	366.1880	366.2180
366.2460	366.2480	366.2780	366.4600	366.7925	366.7930	367.3424
367.3428	367.4500					

Miscellaneous

386.0600	386.5045	388.4000	389.6265	706.3400	706.3850	706.4106
706.4111						

B. Apparel

Apparel

370.8440	372.1020	372.1030	372.1040	372.1050	372.1540	372.3500
372.4500	372.6520	373.1000	373.2200	374.3530	374.3550	374.5040
374.6040	378.1030	378.1540	379.3915	379.3925	379.3930	379.4020
379.4030	379.4050	379.4060	379.4110	379.4140	379.4640	379.4670
379.4910	379.4920	379.5520	379.5545	379.5550	379.5565	379.6220
379.6240	379.7605	379.7620	379.8356	379.8357	379.8358	379.8359
379.9020	379.9562	379.9564	379.9566	379.9568	383.0213	383.0219
383.0222	383.0218	383.0236	383.0305	383.0306	383.0390	383.0505
383.0606	383.0622	383.0631	383.0630	383.0805	383.0820	383.0841
383.0860	383.1319	383.1321	383.1610	383.2205	383.2305	383.2706
383.2710	383.2712	383.2714	383.2715	383.2716	383.2718	383.2721

TURKEY—Appendix B—Continued

[The products covered by these investments are certain textile mill products and apparel, which are currently classified under the item numbers of the Tariff Schedules of the United States, Annotated (TSUSA) listed below.]

383.2722	383.2724	383.2726	383.2728	383.2730	383.2732	383.2736
383.2738	383.2750	383.2752	383.2754	383.2758	383.2807	383.2809
383.2814	383.2816	383.2818	383.2821	383.2820	383.2820	383.2835
383.2910	383.3010	383.3020	383.3030	383.3040	383.3037	383.3038
383.3060	383.3090	383.3200	383.3445	383.3448	383.3465	383.3466
383.3710	383.3770	383.4200	383.4300	383.4702	383.4705	383.4709
383.4711	383.4721	383.4724	383.4726	383.4747	383.4761	383.476
383.4764	383.4816	383.4821	383.4825	383.5026	383.5027	383.5051
383.5054	383.5090	383.5395	383.6310	383.6330	383.6345	383.6360
383.6371	383.6395	383.7010	383.7020	383.7205	383.7210	383.7510
383.7522	383.7532	383.7534	383.7536	383.7538	383.7542	383.7544
383.7546	383.7548	383.7552	383.7554	383.7556	383.7528	383.7558
383.7562	383.7585	383.7764	383.7768	383.7769	383.7770	383.7771
383.7783	383.7881	383.7883	383.7884	383.7887	383.7888	383.7892
383.8012	383.8045	383.8069	383.8071	383.8073	383.8300	383.8400
383.8620	383.8663	383.9015	383.9025	383.9050	383.9056	383.9057
383.9058	383.9059	383.9061	383.9062	383.9063	383.9064	383.9066
383.9225	702.0600	702.8000	704.2000	704.6500	704.8550	704.9000

APPENDIX C.—IMPORTS OF CERTAIN TEXTILE MILL PRODUCTS AND APPAREL FROM THE PHILIPPINES IN 1983

[TARIFF SCHEDULE NUMBERS SUBJECT TO INVESTIGATIONS]

A. TEXTILE MILL PRODUCTS

Yarns

303.1000	303.2040	307.6810	307.6820	307.6830	310.5049
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Cordage

315.3500	315.4500	316.3000	316.5800
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Fabrics

328.1062	328.1063	328.4021	328.4022	328.4024	328.4031	328.4038
328.4042	328.4049	328.4054	328.4057	328.4065	328.4072	328.4074
328.4080	328.4088	335.7500				

Special Constructional Fabrics

347.6040	348.0082	348.0085	348.0095	348.0575	349.1060	351.0500
351.3000	351.4010	351.4610	351.4660	351.8060	352.8060	353.5052
355.2500	355.4530	357.1500	357.7060	357.8060	358.0210	

Textile Furnishings

360.1515	360.1520	360.4225	360.4825	360.7000	360.7800	360.8300
361.4500	361.4800	361.5420	361.5426	361.5620	361.5660	363.0120
363.0515	363.0525	363.2562	363.2564	363.2575	363.2580	363.3020
363.5115	363.8506	363.8509	363.8555	365.5060	365.7825	365.7855
365.7865	365.8100	365.8300	365.8640	365.8660	365.8670	365.8680
366.1540	366.1840	366.1855	366.4600	366.4700	366.4820	366.4840
366.5100	366.5400	366.5740	366.7200	366.7700	366.7925	366.7930
367.5500	367.6025	367.6040	367.6080	367.6500		727.8200

Miscellaneous

385.5000	385.6120	385.6140	385.6300	385.7040	386.0430	386.2000
386.5050	387.3700	389.3000	389.4000	389.5000	389.6270	389.7000

B. APPAREL

Wearing Apparel

370.0800	370.1200	370.1600	370.8420	372.1010	372.1020	372.1030
372.1036	372.1040	372.1060	372.1540	372.1560	372.3500	372.6020
372.7000	372.7520	372.7540	372.2200	374.1000	374.2500	374.3530
374.3550	374.4000	374.6020	376.1600	376.2425	376.2430	376.2470
376.2825	376.2830	376.2846	376.2886	376.5408	376.5609	376.5612
376.5618	378.0545	378.0550	378.0553	378.0560	378.0571	378.0576
378.1035	378.1535	378.1540	378.6030	378.6530	379.0211	379.0212
379.0220	379.0230	379.0240	379.0490	379.0607	379.0609	379.0615
379.0620	379.0624	379.0640	379.0646	379.0840	479.2020	379.2320

APPENDIX C.—IMPORTS OF CERTAIN TEXTILE MILL PRODUCTS AND APPAREL FROM THE PHILIPPINES IN 1983—Continued

[TARIFF SCHEDULE NUMBERS SUBJECT TO INVESTIGATIONS]

379.2360	379.2610	379.2630	379.2830	379.2840	379.3120	379.3130
379.3140	379.3180	379.3334	379.3336	379.3540	379.3905	379.3915
379.3925	379.3930	379.4020	379.4030	379.4040	379.4050	379.4060
379.4140	379.4330	379.4615	379.4620	379.4640	379.4650	379.4660
379.4670	379.5220	379.5520	379.5530	379.5535	379.5540	379.5545
379.5550	379.5560	379.5565	379.5700	379.5800	379.6210	379.6217
379.6219	379.6220	379.6230	379.6240	379.6250	379.6260	379.6270
379.6280	379.6430	379.6470	379.7259	379.7540	379.7547	379.7550
379.7555	379.7580	379.7610	379.7620	379.7630	379.7650	379.8311
379.8318	379.8356	379.8357	379.8358	379.8359	379.8360	379.8420
379.8906	379.8911	379.8915	379.8930	379.8935	379.8940	379.9010
379.9020	379.9030	379.9035	379.9040	379.9100	379.9510	379.9525
379.9530	379.9535	379.9540	379.9550	379.9555	379.9562	379.9564
379.9566	379.9568	379.9575	379.9580	379.9585	379.9650	383.0207
383.0208	383.0212	383.0213	383.0214	383.0216	383.0217	383.0218
383.0219	383.0222	383.0226	383.0228	383.0232	383.0234	383.0236
383.0238	383.0242	383.0246	383.0248	383.0272	383.0305	383.0306
383.0320	383.0330	383.0335	383.0335	383.0340	383.0350	383.0361
383.0390	383.0505	383.0506	383.0507	383.0509	383.0570	383.0606
383.0608	383.0612	383.0614	383.0616	383.0618	383.0622	383.0630
383.0631	383.0638	383.0640	383.0657	383.0805	383.0810	383.0815
383.0820	383.0825	383.0830	383.0835	383.0838	383.0841	383.0844
383.0855	383.0856	383.0859	383.0860	383.1802	383.1804	383.1805
383.1806	383.1807	383.1809	383.1811	383.1812	383.1822	383.1824
383.1841	383.1843	383.1846	383.1848	383.1852	383.1854	383.1880
383.1910	383.1920	383.1922	383.1924	383.1926	383.1928	383.1935
383.1940	383.2005	383.2013	383.2014	383.2016	383.2020	383.2025
383.2035	383.2040	383.2050	383.2052	383.2054	383.2058	383.2060
383.2205	383.2210	383.2212	383.2214	383.2216	383.2225	383.2227
383.2228	383.2229	383.2231	383.2232	383.2233	383.2234	383.2236
383.2237	383.2241	383.2243	383.2245	383.2248	383.2251	383.2255
383.2305	383.2310	383.2315	383.2320	383.3325	383.2330	383.2335
383.2340	383.2350	383.2351	383.2352	383.2354	383.2556	383.2360
383.2365	383.2550	383.2580	383.2590	383.2706	383.2710	383.2712
383.2714	383.2715	383.2716	383.2718	383.2721	383.2722	383.2724
383.2726	383.2728	383.2730	383.2732	383.2736	383.2738	383.2750
383.2814	383.2816	383.2818	383.2820	383.2821	383.2826	383.2828

Headwear

702.1400

Gloves

704.4010 704.4025 704.4504 704.4506 704.4508 704.5015

NOTE.—With regard to the woven cotton fabrics subject to these investigations, the U.S. Department of Commerce has used the U.S. Import Statistical Numbers, which closely parallel the TSUSA numbers, in preparing this appendix. For example, U.S. Import Statistical Number 320.0001 represents TSUSA Numbers 320.0101 through 320.0901, and 326.3098 represents TSUSA Numbers 326.3098 through 326.3998.

Appendix D.—Imports of Certain Textile Mill Products and Apparel From Indonesia in 1983

[Tariff Schedule Numbers Subject to Investigations]

A. Textile Mill Products

Yarns and Threads

310.0250 310.5049

Woven Fabrics

320.0001	320.0012	320.0013	320.0019	320.0032	320.0033	320.0034
320.0043	320.0044	320.0045	320.0062	320.0063	320.0071	320.0077
320.1019	320.1034	320.1045	320.1071	320.1077	322.1015	322.1017
322.1029	322.1036	322.1040	322.1047	322.1055	322.1056	322.1065
322.1068	322.1070	322.1079	322.1097	322.3003	322.3018	322.3021
322.3022	322.3024	322.3027	322.3038	322.3042	322.3049	322.3054
322.3057	322.3065	322.3072	322.3074	322.3080	322.3098	322.4003
322.4021	322.4022	322.4024	322.4031	322.4038	322.4042	322.4049
322.4054	322.4057	322.4065	322.4072	322.4074	322.4080	322.4098
322.5021	322.5022	322.5024	322.5031	322.5038	322.5042	322.5049
322.5054	322.5057	322.5065	322.5072	322.5074	322.5080	322.5098

Appendix D.—Imports of Certain Textile Mill Products and Apparel From Indonesia in 1983—
Continued

[Tariff Schedule Numbers Subject to Investigations]

322.8003	322.8021	322.8022	322.8024	322.8038	322.8042	322.8049
322.8054	322.8057	322.8065	322.8072	322.8074	322.8080	322.8098
325.8021	325.8022	325.8024	325.8031	326.1050	326.1051	326.1052
326.1085	326.1089	326.1091	326.1095	326.3016	326.3018	326.3021
326.3022	326.2023	326.3024	326.3027	326.3031	326.3038	326.3042
326.3049	326.3054	326.3057	326.3065	326.3069	326.3072	326.3073
326.3074	326.3080	326.3088	332.4040	338.5021	338.5024	338.5030
338.5031	338.5035	338.5036	338.5039	338.5064	338.5069

Special Construction Fabrics

347.3380

Textile Furnishings

361.4500	363.4500	363.5115	365.7825	365.7865	366.2740	366.2780
366.4600	366.4700	366.7925	366.7930	727.8630

Luggage and Handbags

706.3400	706.3640	706.3650	706.3680	706.4105	706.4111	706.4140
706.4150

Miscellaneous

386.1500	386.4000	386.5045	389.3000	389.7000
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B. Apparel

Wearing Apparel

372.1060	372.1540	372.1560	372.2000	372.7000	372.7520	378.1540
379.0220	379.0620	379.0640	379.0642	379.0646	379.0810	379.2350
379.2630	379.3120	379.3940	379.4010	379.4020	379.4040	379.4050
379.4330	379.4630	379.4640	379.4650	379.4660	379.4670	379.5210
379.5220	379.5510	379.5520	379.5525	379.5530	379.5535	379.5540
379.5545	379.5550	379.5560	379.5565	379.5800	379.6210	379.6220
379.6230	379.6240	379.6250	379.6470	379.8915	379.9025	379.9030
379.9040	379.9250	379.9530	379.9535	379.9540	379.9545	379.9550
379.9555	379.9570	379.9575	379.9580	379.9585	379.9641	379.9650
383.0219	383.0222	383.0226	383.0228	383.0232	383.0234	383.0238
383.0242	383.0246	383.0248	383.0262	383.0264	383.0266	383.0268
383.0272	383.0305	383.0335	383.0361	383.0505	383.0506	383.0507
383.0509	383.0606	383.0608	383.0612	383.0614	383.0618	383.0622
383.0631	383.0616	383.0630	383.0638	383.0640	383.0805	383.0835
383.0838	383.0841	383.0856	383.0859	383.0860	383.1305	383.1802
383.1804	383.1805	383.1806	383.1807	383.1822	383.1824	383.1841
383.1910	383.1915	383.1920	383.1922	383.1924	383.1926	383.1928
383.2005	383.2013	383.2014	383.2020	383.2025	383.2035	383.2040
383.2050	383.2052	383.2058	383.2060	383.2205	383.2210	383.2212
383.2214	383.2225	383.2227	383.2228	383.2229	383.2231	383.2232
383.2233	383.2234	383.2235	383.2236	383.2237	383.2239	383.2241
383.2243	383.2245	383.2248	383.2251	383.2255	383.2305	383.2315
383.2320	383.2325	383.2330	383.2335	383.2340	383.2350	383.2352
383.2354	383.2356	383.2360	383.2365	383.2535	383.2550	383.2590
383.2710	383.2712	383.2714	383.2715	383.2716	383.2718	383.2721
383.2722	383.2724	383.2726	383.2728	383.2730	383.2732	383.2736
383.2738	383.2814	383.2816	383.2818	383.2821	383.2826	383.2828
383.2835	383.2910	383.3030	383.3040	383.3060	383.3060	383.3090
383.3200	383.3430	383.3435	383.3445	383.3446	383.3448	383.3450
383.3460	383.3465	383.3466	383.3770	383.4015	383.4300	383.4702
383.4704	383.4705	383.4707	383.4709	383.4711	383.4716	383.4717
383.4718	383.4720	383.4721	383.4724	383.4726	383.4747	383.4748
383.4750	383.4753	383.4754	383.4756	383.4761	383.4762	383.4764
383.4765	383.4821	383.4825	383.4900	383.5026	383.5027	383.5028
383.5031	383.5034	383.5037	383.5043	383.5051	383.5078	383.5082
383.5084	383.5086	383.5088	383.5090	383.5295	383.5395	383.6371
383.7887	383.7888	383.7892	383.8002	383.8007	383.8009	383.8011
383.8012	383.8014	383.8017	383.8019	383.8024	383.8026	383.8026
383.8030	383.8045	383.8048	383.8050	383.8052	383.8069	383.8071
383.8073	383.8115	383.8137	383.8139	383.8145	383.8162	383.8164
383.8605	383.8620	383.8635	383.8645	383.8660	383.8663	383.8669
383.8670	383.8610	383.9005	383.9010	383.9015	383.9020	383.9025

Appendix D.—Imports of Certain Textile Mill Products and Apparel From Indonesia in 1983—
Continued

[Tariff Schedule Numbers Subject to Investigations]

383.9027	383.9029	383.9050	383.9051	383.9056	383.9057	383.9058
383.9059	383.9061	383.9062	383.9063	383.9064	383.9066	383.9068
383.9069	383.9070	383.9210	383.9220	383.9225	383.9235	383.9240
383.9245	383.9255	383.9257	383.9270	383.9276	383.9290	383.9291
383.2835	383.2910	383.3010	383.3020	383.3030	383.3037	383.3038
383.3040	383.3060	383.3069	383.3080	383.3085	383.3090	383.3200
383.3405	383.3415	383.3420	383.3430	383.3435	383.3445	383.3448
383.3450	383.3452	383.3460	383.3465	383.3466	383.3600	383.4015
383.4200	383.4300	383.4702	383.4704	383.4705	383.4707	383.4709
383.4711	383.4716	383.4717	383.4718	383.4720	383.4721	383.4724
383.4726	383.4747	383.4748	383.4750	383.4753	383.4754	383.4756
383.4758	383.4760	383.4761	383.4762	383.4764	383.4765	383.4816
383.4818	383.4820	383.4821	383.4823	383.4825	383.5026	383.5028
383.5029	383.5031	383.5032	383.5033	383.5034	383.5037	383.5040
383.5041	383.5042	383.5043	383.5044	383.5051	383.5054	383.5057
383.5060	383.5082	383.5086	383.5088	383.5090	383.5295	383.5304
383.5305	383.5316	383.5369	383.5385	383.5395	383.5825	383.5845
383.6330	383.6340	383.6371	383.6395	383.7205	383.7210	383.7510
383.7520	383.7522	383.7532	383.7534	383.7536	383.7538	383.7542
383.7544	383.7546	383.7548	383.7552	383.7554	383.7556	383.7881
383.7883	383.7886	383.7887	383.7888	383.7892	383.8002	383.8007
383.8009	383.8011	383.8012	383.8014	383.8017	383.8019	383.8024
383.8026	383.8028	383.8030	383.8045	383.8048	383.8050	383.8052
383.8069	383.8071	383.8073	383.8108	383.8110	383.8114	383.8115
383.8116	383.8117	383.8137	383.8139	383.8141	383.8143	383.8147
383.8156	383.8158	383.8162	383.8164	383.8300	383.8605	383.8620
383.8621	383.8622	383.8630	383.8635	383.8645	383.8650	383.8660
383.8661	383.8663	383.8665	383.8669	383.8670	383.9010	383.9015
383.9020	383.9025	383.9027	383.9029	383.9032	383.9035	383.9040
383.9042	383.9050	383.9051	383.9056	383.9057	383.9058	383.9059
383.9061	383.9062	383.9063	383.9064	383.9066	383.9068	383.9069
383.9070	383.9072	383.9074	383.9076	383.9205	383.9210	383.9211
383.9215	383.9225	383.9230	383.9235	383.9240	383.9245	383.9246
383.9265	383.9270	383.9273	383.9276	383.9291	383.9562	383.9564
383.9566	383.9568	383.9570	383.9572	383.9574	383.9576	383.9578
383.9579						

Headwear

702.5600	703.0510	703.0520	703.0530	703.0540	703.0550	703.0560
703.1000	703.1610	703.1620	703.1630	703.1640	703.1650

Gloves

704.1020	704.2000	704.2500	704.3210	704.3215	704.3240	704.4010
704.4504	704.4506	704.4508	704.5015	704.6500	704.8515	704.8525
704.8550	704.9000	705.8520			

Luggage and Handbags

706.3410	706.3420	706.3430	706.3200	706.3640	706.3680	706.3640
706.3850	706.4106	706.4121	706.4140	706.4144	706.4152

[FR Doc. 85-9276 Filed 4-16-85; 8:45 am]

BILLING CODE 3510-05-M

National Oceanic and Atmospheric
AdministrationMarine Mammals; Application for
Permit; Glen Oak Zoo

Notice is hereby given that an Applicant has applied in due form for a Permit to take marine mammals as authorized by the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361-1407), and the Regulations Governing

the Taking and Importing of Marine Mammals (50 CFR Part 216).

1. Applicant:
 - a. Name Glen Oak Zoo (P357), Peoria Park District.
 - b. Address 2218 N. Prospect Road, Peoria, Illinois 61603.
2. Type of Permit: Public Display.
3. Name and Number of Marine Mammals: California sea lions (*Zalophus californianus*) 2.
4. Type of Take: Captive maintenance.
5. Location of Activity: No take from the wild is involved.
6. Period of Activity: One (1) year.

The arrangements and facilities for transporting and maintaining the marine mammals requested in the above described application have been inspected by a licensed veterinarian, who has certified that such arrangements and facilities are adequate to provide for the well-being of the marine mammals involved.

Concurrent with the publication of this notice in the *Federal Register*, the Secretary of Commerce is forwarding copies of this application to the Marine Mammal Commission and the Committee of Scientific Advisors.

Written data or views, or requests for a public hearing on this application should be submitted to the Assistant Administrator for Fisheries, National Marine Fisheries Service, U.S. Department of Commerce, Washington, D.C. 20235, within 30 days of the publication of this notice. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular application would be appropriate. The holding of such hearing is at the discretion of the Assistant Administrator for Fisheries.

All statements and opinions contained in this application are summaries of those of the Applicant and do not necessarily reflect the views of the National Marine Fisheries Service.

Documents submitted in connection with the above application are available for review in the following offices:

Assistant Administrator for Fisheries,
National Marine Fisheries Service,
3300 Whitehaven Street, N.W.,
Washington, D.C.,

Regional Director, Southeast Region,
National Marine Fisheries Service,
Southeast Region, 4950 Koger
Boulevard, St Petersburg, Florida
333702; and

Regional Director, Northeast Region,
National Marine Fisheries Service,
Federal Building, 14 Elm Street,
Gloucester, Massachusetts, 01930-
3799.

Dated: April 11, 1985.

William G. Gordon,

Assistant Administrator for Fisheries,
National Marine Fisheries Service.

[FR Doc. 85-9191 Filed 4-16-85; 8:45 am]

BILLING CODE 3510-22-M

Marine Mammals; Issuance of Permit;
Ms. Susan Shane

On February 27, 1985, notice was published in the *Federal Register* (50 FR 7946) that an application had been filed by Ms. Susan Shane, 250 Cottini Way, Santa Cruz, California 95060, for a Permit to take an unspecified number of

Atlantic bottlenose dolphins (*Tursiops truncatus*) for the purpose of scientific research.

Notice is hereby given that on April 11, 1985 as authorized by the provisions of the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361-1407), the National Marine Fisheries Service issued a Permit for the above taking, subject to certain conditions set forth therein.

The Permit is available for review by interested persons in the following offices:

Assistant Administrator for Fisheries,
National Marine Fisheries Service,
3300 Whitehaven Street, N.W.,
Washington, D.C., and
Regional Director, Southeast Region,
National Marine Fisheries Service,
9450 Koger Boulevard, St. Petersburg,
Florida 33702; and
Regional Director, Southwest Region,
National Marine Fisheries Service, 300
South Ferry Street, Terminal Island,
California 90731

Dated: April 11, 1985.

William G. Gordon,

*Assistant Administrator for Fisheries,
National Marine Fisheries Service.*
[FR Doc 85-9190 Filed 4-16-85; 8:45 am]

BILLING CODE 3510-22-M

Marine Mammals; Issuance of Permit; Center for Coastal Marine Studies

On January 9, 1985, notice was published in the *Federal Register* (50 FR 1100) that an application has been filed by the Center for Coastal Marine Studies, University of California, Santa Cruz, California, for a permit to take 4,940 northern elephant seals (*Mirounga angustirostris*) a year for five years for tagging and physiological studies.

Notice is hereby given that on April 8, 1985, as authorized by the provisions of the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361-1407), the National Marine Fisheries Service issued a Permit for the above taking, subject to certain conditions set forth therein.

The Permit is available for review by interested persons in the following offices:

Assistant Administrator for Fisheries,
National Marine Fisheries Service,
3300 Whitehaven Street, N.W.,
Washington, D.C.; and
Regional Director, Southwest Region,
National Marine Fisheries Service, 300
South Ferry Street, Terminal Island,
California 90731.

Dated: April 9, 1985.

William G. Gordon,

*Assistant Administrator for Fisheries,
National Marine Fisheries Service.*
[FR Doc. 85-9195 Filed 4-16-85; 8:45 am]

BILLING CODE 3510-22-M

Request for a Modification to a General Permit

On February 15, 1985, a General Permit in Category 1: Towed or Dragged Gear was issued to Scan Ocean, Inc. to take 5 harbor seals and 15 cetaceans during commercial fishing operations in the North Atlantic Ocean during 1985.

During the spring mackerel fishing seasons, the Netherlands fleet reported an incidental take of 18 cetaceans; 8 common dolphins and 10 pilot whales. In order to cover this incidental take and to conduct fishing operations throughout the rest of the year, the Permit Holder has requested a modification of their general permit to allow an incidental take of an additional cetaceans.

The application is available for review in the Office of the Assistant Administrator for Fisheries, National Marine Fisheries Service, 3300 Whitehaven Street, N.W., Washington, D.C.

Interested parties may submit written comments on this application within 30 days of the date of this notice to the Assistant Administrator for Fisheries, National Marine Fisheries Service, Washington, D.C. 20235.

Dated: April 11, 1985.

William G. Gordon,

*Assistant Administrator for Fisheries,
National Marine Fisheries Service.*
[FR Doc. 85-9196 Filed 4-16-85; 8:45 am]

BILLING CODE 3510-22-M

Request for a Modification to a General Permit

On February 21, 1985, a General Permit in Category 1: Towed or Dragged Gear was issued to FEDERPESCA, Rome, Italy, to take 5 harbor seals and 10 cetaceans during commercial fishing operations in the North Atlantic Ocean during 1985.

During the spring squid fishing season, the Italian fleet reported an incidental take of 32 cetaceans; 28 common dolphins and 4 unidentified. In order to cover this incidental take and to conduct summer squid fishing commencing in July, the Permit Holder has requested a modification of their general permit to allow an incidental take of an additional 25 cetaceans.

The application is available for review in the Office of the Assistant

Administrator for Fisheries, National Marine Fisheries Service, 3300 Whitehaven Street, N.W., Washington, D.C.

Interested parties may submit written comments on the application within 30 days of the date of this notice to the Assistant Administrator for Fisheries, National Marine Fisheries Service, Washington, D.C. 20235.

Dated: April 11, 1985.

William G. Gordon,

*Assistant Administrator for Fisheries,
National Marine Fisheries Service.*
[FR Doc. 85-9194 Filed 4-16-85; 8:45 am]

BILLING CODE 3510-22-M

Marine Mammals; Application for Permit; Sea World, Inc.

Notice is hereby given that an Applicant has applied in due form for a Permit to take marine mammals as authorized by the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361-1407), and the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR Part 216).

1. Applicant:

a. Name: Sea World, Inc. (P2P).
b. Address: 1720 South Shores Road,
Mission Bay, San Diego, California
92109.

2. Type of Permit: Public Display.

3. Name and Number of Marine Mammals: false killer whales (*Pseudorca crassidens*), 6.

4. Type of Take: Import.

5. Location of Activity: Import from Japan.

6. Period of Activity: 3 years.

The arrangements and facilities for transporting and maintaining the marine mammals requested in the above described application have been inspected by a licensed veterinarian, who has certified that such arrangements and facilities are adequate to provide for the well-being of the marine mammals involved.

Concurrent with the publication of this notice in the *Federal Register*, the Secretary of Commerce is forwarding copies of this application to the Marine Mammal Commission and the Committee of Scientific Advisors.

Written data or views, or requests for a public hearing on this application should be submitted to the Assistant Administrator for Fisheries, National Marine Fisheries Service, U.S. Department of Commerce, Washington, D.C. 20235, within 30 days of the publication of this notice. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular application

would be appropriate. The holding of such hearing is at the discretion of the Assistant Administrator for Fisheries.

All statements and opinions contained in this application are summaries of those of the Applicant and do not necessarily reflect the views of the National Marine Fisheries Service.

Documents submitted in connection with the above application are available for review in the following offices:

Assistant Administrator for Fisheries, National Marine Fisheries Service, 3300 Whitehaven Street, NW., Washington, D.C.

Regional Director, Northeast Region, National Marine Fisheries Service, Federal Building, 14 Elm Street, Gloucester, Massachusetts 01930-3799.

Regional Director, Southeast Region, National Marine Fisheries Service, 9450 Koger Boulevard, St. Petersburg, Florida 33702.

Regional Director, Southwest Region, National Marine Fisheries Service, 300 South Ferry Street, Terminal Island, California 90731.

Dated: April 11, 1985.

William G. Gordon,

Assistant Administrator for Fisheries,
National Marine Fisheries Service.

[FR Doc. 85-9296 Filed 4-16-85; 8:45 am]

BILLING CODE 3510-22-M

Marine Fisheries Advisory Committee; Renewal

In accordance with the provisions of the Federal Advisory Committee Act, 5 U.S.C. App. 2 and General Services Administration (GSA) Interim Rule on Federal Advisory Committee Management, 41 CFR Part 101-6, as amended, and after consultation with GSA, the Secretary of Commerce has determined that the renewal of the Marine Fisheries Advisory Committee is in the public interest in connection with the performance of duties imposed on the Department by law. The Committee was first established in February 1971, and is due to terminate on April 11, 1985. Its original purpose was to advise the Secretary of Commerce on all living marine resource matters which are the responsibility of the Department of Commerce. It served to ensure that the living marine resource policies and programs of this Nation were adequate to meet the needs of commercial and recreational fishermen, environmental, state, consumer, and other national interests. This objective is being achieved. The Committee is playing an important role in the discussion and development of fisheries policy for the Department of Commerce. Its recommendations are of substantial

value to the National Oceanic and Atmospheric Administration and the National Marine Fisheries Service as well as the Department.

In renewing the Committee, the Secretary has established for it the continuation of this objective for the next two years. Drawing on its experiences and the expertise of its individual members, the Committee is to advise the Secretary of Commerce on all living marine resource matters which are the responsibility of the Department of Commerce and to ensure that the living marine resource policies and programs of this Nation are adequate to meet the needs of commercial and recreational fishermen, environmental, state, consumer, and other national interests. Research indicates that the Committee's function cannot be accomplished by any organizational element or other committee of the Department.

The Committee will continue with a balanced representation of 21 members, chaired by the Administrator of the National Oceanic and Atmospheric Administration, and will operate in compliance with the provisions of the Federal Advisory Committee Act.

Copies of the Committee's revised charter will be filed with appropriate committees of the Congress and with the Library of Congress.

Inquiries or comments may be addressed to the Committee Control Officer, Ann Smith, Executive Secretary, Marine Fisheries Advisory Committee, Constituent Affairs Staff, National Marine Fisheries Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce, Washington, D.C., 20234, telephone: (202) 634-9563, or the Department's Committee Management Analyst, telephone: (202) 377-4217.

Dated: April 11, 1985.

Katherine M. Bulow,

Assistant Secretary for Administration.

[FR Doc. 85-9222 Filed 4-16-85; 8:45 am]

BILLING CODE 3510-06-M

DEPARTMENT OF DEFENSE

Corps of Engineers, Department of the Army

Intent To Prepare a Draft Environmental Impact Statement (DEIS) for a Proposed Water Supply Impoundment on Crump's Millpond in the City of Suffolk, VA

AGENCY: U.S. Army Corps of Engineers, DOD.

ACTION: Notice of Intent to Prepare a Draft Environmental Impact Statement (DEIS).

SUMMARY:

1. Proposed Action: The City of Suffolk proposes to build an earthen impoundment structure across Crump's Millpond, an existing impoundment of Chuckatuck Creek, north of the Chuckatuck area of Suffolk, Virginia. The impounded lake would have a normal pool area of approximately 485 acres with a normal pool elevation of approximately 40 feet mean sea level. As a water supply reservoir, the lake could supply a maximum safe yield of 2.4 million gallons per day. A significant portion of the area to be flooded consists of wetlands.

2. Alternatives: Alternatives which will be investigated include, but will not be limited to site alternatives in and around the Chuckatuck area of Suffolk, groundwater use, conservation and no project.

3. Scoping Process: Informal pre-application scoping meetings were held with State and Federal agencies in the fall of 1984. Significant issues which have already been identified include wetland destruction and mitigation, impacts to anadromous fishes and watershed development. A public notice requesting written scoping comments will be published on or about April 8, 1985.

4. Public Meetings: The public notice mentioned above will also announce the date and location of a public scoping meeting.

5. DEIS Availability: It is estimated that the DEIS will be available to the public for review and comments in the fall of 1985.

ADDRESS: Questions about the proposed actions and DEIS can be answered by: Ms. Pamela Painter, U.S. Army Engineer District, Norfolk, 803 Front Street, Norfolk, Virginia 23510, (804) 441-3654-COM, 827-3654-FTS.

Dated: April 8, 1985.

Ronald L. Hawthorne,

Major, Corps of Engineers, Acting District Engineer.

[FR Doc. 85-9197 Filed 4-16-85; 8:45 am]

BILLING CODE 3710-EN-M

DEPARTMENT OF EDUCATION

Office of Postsecondary Education

Guaranteed Student Loan Program and PLUS Program

AGENCY: Department of Education.

ACTION: Notice of Special Allowance for Quarter Ending March 31, 1985.

The Assistant Secretary for Postsecondary Education announces a special allowance to holders of eligible loans made under the Guaranteed Student Loan Program (GSLP) or the PLUS Program. This special allowance is provided for under section 438 of the Higher Education Act of 1965 (the Act), as amended (20 U.S.C. 1087-1). Except for loans subject to section 438(b)(2)(B) of the Act, 20 U.S.C. 1087-1(b)(2)(B), for the quarter ending March 31, 1985, the special allowance will be paid at the following rates:

	Applicable interest rate (percent)	Annual special allowance rate (percent)	Special allowance rate (percent) for quarter ending Mar. 31, 1985
GSLP loans or PLUS loans made prior to Oct. 1, 1981.	7	5.00	1.25
	9	3.00	0.75
GSLP loans or PLUS loans made on or after Oct. 1, 1981.	7	4.96	1.24
	8	3.96	0.99
	9	2.96	0.74
	12	0.00	0.00
	14	0.00	0.00

The Assistant Secretary determines the special allowance rate in the manner specified in the Act for loans at each applicable interest rate by making the following four calculations:

(a) *Step 1.* Determine the average bond equivalent rate of the 91-day Treasury bills auctioned during the quarter for which this notice applies:

(b) *Step 2.* Subtract from that average the applicable interest rate (7, 8, 9, 12, or 14 percent) of loans for which a holder is requesting payment;

(c) *Step 3.* (1) Add 3.5 percent to the remainder; and

(2) In the case of loans made before October 1, 1981, round the sum upward to the nearest one-eighth of one percent;

(d) *Step 4.* Divide the resulting percent in Step 3 (either (c)(1) or (c)(2), as applicable) by four.

FOR FURTHER INFORMATION CONTACT:

Nancy Eakin, Program Specialist, or Larry Oxendine, Chief, Policy Section, Guaranteed Student Loan Branch, Division of Policy and Program Development, Department of Education on (202) 245-2475.

Dated: April 12, 1985.

(Catalog of Federal Domestic Assistance No. 84-032, Guaranteed Student Loan Program and PLUS Program)

Edward M. Elmendorf,

Assistant Secretary for Postsecondary Education.

[FR Doc. 85-9254 Filed 4-16-85; 8:45 am]

BILLING CODE 4000-01-M

DEPARTMENT OF ENERGY**Office of Energy Research****Magnetic Fusion Advisory Committee; Open Meeting**

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770), notice is hereby given of the following meeting:

Name: Magnetic Fusion Advisory Committee.

Date and time: May 8-9, 1985 from 9:00 a.m. to 5:00 p.m.

Location: University of California at Los Angeles, Ackerman Student Union, 2nd Floor Lounge.

Contact: Rosalie Weller, Office of Fusion Energy, ER-50, U.S. Department of Energy, Mail Stop G-226, Washington, D.C. 20545. Phone: (301)-853-3347.

Purpose of the Committee: To provide advice to the Secretary of Energy on the Department's Magnetic Fusion Energy Program, including periodic reviews of elements of the program and recommendations of changes based on scientific and technological advances or other factors; advice on long-range plans, priorities, and strategies to demonstrate the scientific and engineering feasibility of fusion; advice on recommended appropriate levels of funding to develop those strategies and to help maintain appropriate balance between competing elements of the program.

Tentative Agenda Outline

1. Status of International Fusion Planning—Clarke
2. Report of MFAC Panel X Reviewing High Power Density Systems
 - A. Panel Charge and Process—Davidson, Gross
 - B. Introduction, Background and Issues—Linford
 - C. Panel Findings
 - Physics Issues—Logan
 - Parametric Studies, Reactor and Technology Issues—Baker
 - D. Panel Recommendations—Conn
3. MFAC Discussion and Recommendations
4. Public Discussion
5. MFAC Panel Reviewing Fusion System Studies—Status Report—Stacey
6. TFTR Results and Status—Meade
7. Initial Phase of Technical Planning Activity—Baker
8. New Charge Areas—Clarke, Davidson
9. MFAC Discussion and Recommendations

10. Public Discussion

Public Participation: The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Members of the public who wish to make oral statements pertaining to agenda items should contact Rosalie Weller at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable provision will be made to include the presentation on the agenda. The Chairperson of the Committee is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business.

Minutes: Available approximately 30 days following the meeting.

Issued at Washington, D.C., on April 12, 1985.

J. Robert Franklin,

Deputy Advisory Committee Management Officer.

[FR Doc. 85-9242 Filed 4-16-85; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket Nos. ER84-631-002, et al.]

Electric Rate and Corporate Regulation Filings; Arizona Public Service Co. et al.

Take notice that the following filings have been made with the Commission:

1. Arizona Public Service Company

[Docket No. ER84-631-002]

April 11, 1985.

Take notice that on March 20, 1985, Arizona Public Service Company (APS), submitted for filing a compliance report pursuant to the Commission's Letter Order dated October 1, 1984.

APS submitted copies of the Rate Sheets, entitled Amendment No. 1, which are appended for inclusion in SCE's FERC Rate Schedule No. 120. APS requests that the Rate Sheets be designated accordingly, and that this Docket be terminated with regard to the wholesale power rates for SCE.

Comment date: April 26, 1985, in accordance with standard Paragraph H at the end of this notice.

2. Holyoke Water Power Company, Holyoke Power and Electric Company

[Docket No. ER84-554-001]

April 11, 1985.

Take notice that on February 15, 1985, Holyoke Water Power Company (HWP) and Holyoke Power and Electric Company (HP&E) submitted for filing a

refund report pursuant to the Commission's letter dated January 29, 1985, approving the Settlement Agreement between the parties.

The enclosure to the Commission's letter incorrectly identified the effective date as June 30, 1985 for HP&E's tariff applicable to the Town of South Hadley. The effective date should have been listed as June 20, 1985. Further, HWP and HP&E hereby inform the Commission that there will be no refunds to report.

Comment date: April 26, 1985, in accordance with Standard Paragraph H at the end of this notice.

3. Kentucky Utilities Company

[Docket No. EC85-12-000]

April 12, 1985.

Take notice that on April 1, 1985, Kentucky Utilities Company (KU) submitted for filing an application for authority pursuant to section 208 of the Federal Power Act, to acquire from Old Dominion Power Company (Old Dominion) certain of the latter's securities.

Specifically, KU seeks to acquire from Old Dominion unsecured promissory notes of Old Dominion from time to time during the years 1985 and 1986 provided that the maximum aggregate principal amount of such note outstanding at any time shall not exceed \$41,750,000.

Comment date: May 1, 1985, in accordance with Standard Paragraph E at the end of this notice.

4. El Paso Electric Company

[Docket No. ES85-36-000]

April 12, 1985.

Take notice that on April 2, 1985, El Paso Electric Company (Applicant) filed an application with the Federal Energy Regulatory Commission (Commission) seeking authority pursuant to section 204 of the Federal Power Act to issue up to 300,000 shares of Common Stock, no par value, pursuant to the Employee Stock Compensation Plan and applying for an exemption of such issuance from the competitive bidding requirements of the Commission.

Comment date: May 2, 1985, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the

comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

H. Any person desiring to be heard or to protest this filing should file comments with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington D.C. 20426, on or before the comment date. Comments will be considered by the Commission in determining the appropriate action to be taken. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,
Secretary.

[FR Doc. 85-9274 Filed 4-16-85; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP85-106-001]

Proposed Change in FERC Gas Tariff; Lawrenceburg Gas Transmission Corp.

April 12, 1985.

Take notice that on April 4, 1985, Lawrenceburg Gas Transmission Corporation tendered for filing one (1) substitute gas tariff sheet to its FERC Gas Tariff, First Revised Volume No. 1, dated as issued on April 2, 1985, proposed to become effective February 28, 1985, and identified as follows: Substitute Thirty-six Revised Sheet No. 4

Lawrenceburg states that its substitute tariff sheet modifies its previously approved restatement of its base tariff rates in this docket pursuant to § 154.38(d)(4)(vi), because of a subsequent reduction in its February 1, 1985 purchased gas adjustment (PGA) rate that was rolled into its restated base rate.

Lawrenceburg states that copies of its filing were served upon its jurisdictional customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with § 385.214 and 385.211 of the Commission's Rules of Practice and Procedure. All such petitions or protests should be filed on or before April 19, 1985. Protests will be considered by the Commission in determining the appropriate action to be

taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,
Secretary.

[FR Doc. 85-9272 Filed 4-16-85; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. GT85-14-000]

Northern Natural Gas Co., Division of InterNorth, Inc.; Filing

April 12, 1985

Take Notice that on April 5, 1985, Northern Natural Gas Company, Division of InterNorth, Inc. (Northern), tendered for filing to become a part of Northern Natural Gas Company's (Northern) F.E.R.C. Gas Tariff, Third Revised Volume No. 1, Thirteenth Revised Sheet No. 96.

This sheet reflects a revision in the Directory of Communities served concerning the Operational Zone listing for Interstate Power Company.

Any person desiring to be heard or to protect said filing should file a petition to intervene or a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with the Commission's Rules of Practice & Procedure (18 CFR) 385.211, 385.214). All such petitions or protests should be filed on or before April 19, 1985. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene.

Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,
Secretary.

[FR Doc. 85-9273 Filed 4-16-85; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[OPP-30242; PH-FRL 2817-8]

Janssen Pharmaceutica; Application To Register a Pesticide Product

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of an application to register a pesticide product containing an active ingredient not included in any previously registered product pursuant to the provision of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

DATE: Comment by May 17, 1985.

ADDRESS: By mail submit comments identified by the document control number [OPP-30252] and the file number (43813-O) to:

Information Services Section (TS-757C), Program Management and Support Division, Attn: Product Manager (PM) 21, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460. In person, bring comments to: Rm. 236 CM#2, Attn: PM 21, Registration Division (TS-767C), Environmental Protection Agency, 1921 Jefferson Davis Highway, Arlington, VA.

Information submitted in any comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice to the submitter. All written comments will be available for public inspection in Rm. 236 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Henry Jacoby, PM 21, (703-557-1900).

SUPPLEMENTARY INFORMATION: Janssen Pharmaceutica, PO Box 344, Bear Tavern Road, Washington Crossing, NJ 08560, has submitted an application to EPA to register the wood preservative fungicide, Rodowood Technical, EPA File Symbol 43813-O, containing the active ingredient 1-[(2-(2,4-dichlorophenyl)-1,3-dioxolan-2-yl)methyl]-1H-1,2,4-triazole at 85 percent, pursuant to the provision of section 3(c)(4) of FIFRA. The application proposes that the product be classified for general use for formulation of wood preservatives only. Notice of receipt of this application does not imply a decision by the Agency on the application.

Notice of approval or denial of an application to register a pesticide product will be announced in the *Federal Register*. The procedure for requesting data will be given in the

Federal Register if an application is approved.

Comments received within the specified time period will be considered before a final decision is made; comments received after the time specified will be considered only to the extent possible without delaying processing of the application.

Written comments filed pursuant to this notice, will be available in the Program Management and Support Division (PMSD) office at the address provided from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. It is suggested that persons interested in receiving the application file, telephone the PMSD office (703-557-3262), to ensure that the file is available on the date of intended visit.

(Sec. 3(c)(4) of FIFRA, as amended)

Dated: March 29, 1985.

Douglas O. Camp,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 85-8819 Filed 4-16-85; 8:45 am]

BILLING CODE 6560-50-M

[OPP-50637; FRL-2819-5]

Sodium Fluoroacetate (Compound 1080); Receipt of Application for an Experimental Use Permit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received an application from the United States Department of the Interior (USDI) Fish and Wildlife Service for an Experimental use permit (EUP), 6704-EUP-EI. The application proposes allowing the use of 0.66 pound of sodium fluoroacetate (Compound 1080) in single lethal dose baits on Kiska Island, Alaska, to eradicate the Arctic fox in order to benefit the endangered Aleutian Canada Goose. USDI proposes to treat a total of 6,128 acres. The application also proposes that the permit run for 2 years starting in the fall of 1985.

DATE: Written comments must be received on or before May 17, 1985.

ADDRESS: Comments, in triplicate, should bear the docket control number OPP-50637 and be submitted to: Program Management and Support Division (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460.

A copy of the USDI application and copies of any public comments filed regarding this notice will be made available for public inspection in Rm.

236, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202 from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: William Miller, Product Manager (PM) 16, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 211, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703-557-2600).

SUPPLEMENTARY INFORMATION: The USDI's experimental use permit application requests that EPA approve experimental use of Compound 1080 in up to 100,000 single lethal dose baits to control the Arctic fox. The USDI has requested that the EUP be granted to allow it to develop information relating to the efficacy of single lethal dose baits (SDBs). The application proposed that the testing be conducted on Kiska Island, Aleutian Islands, Alaska. Kiska is about 22 miles long and 1.5 to 6.2 miles wide and contains 69,598 acres.

The USDI contends that prior to the introduction of Arctic foxes by man, the Aleutian Canada Goose (ACG) was a common breeding bird throughout the Aleutian Islands. Foxes subsequently eradicated the ACG on all islands except Buldir (these predators were not introduced on Buldir because the island is very difficult to access by boat). If the ACG population is to recover from its current endangered status, its breeding range must be expanded beyond Buldir Island. The breeding range is apparently limited only by the presence of Arctic foxes on the islands. Foxes were eradicated on several small islands through a combination of trapping, shooting, and use of M-44s. The logistical difficulties involved in maintaining a successful operational program in the remote Aleutian Islands makes the eradication of Arctic foxes on any of the large islands an extremely difficult, time-consuming, and expensive task. The USDI believes that if expansion of the breeding population of the endangered ACG and its subsequent recovery is to be achieved, a more efficient and effective method to eliminate Arctic foxes must be found.

The USDI proposes a three-part experimental design to (1) determine the acute toxicity of sodium fluoroacetate to Arctic foxes, (2) develop well-accepted and consistently lethal Compound 1080-treated SDBs, and (3) determine the feasibility of using 1080 treated SDBs as the primary tool for eradicating Arctic foxes on the Aleutian Islands Unit, Alaska Maritime National Wildlife Refuge (AMNWR).

If upon completion of this study positive effects outweigh the negative, the USDI intends to pursue a section 3 registration of this specific use.

Because of the regulatory history of Compound 1080, the Agency has determined that this application may be of regional or national significance. Therefore, in accordance with 40 CFR 171.11(a), the Agency is soliciting public comments on this request by the USDI for an experimental use permit for SDBs containing Compound 1080.

Dated: April 5, 1985.

Robert V. Brown,
Acting Director, Registration Division, Office
of Pesticide Programs.

[FR Doc. 85-9203 Filed 4-16-85; 8:45 am]

BILLING CODE 6560-50-M

[PF-407; FRL-2818-8]

Certain Companies, Pesticide Tolerance Petitions; Monsanto Co. et al.

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received pesticide,
food/feed additive petitions relating to
the establishment of tolerances for
certain pesticide chemicals in or on
certain agricultural commodities.

ADDRESS: By mail, submit comments
identified by the document control
number [PF-407] and the petition
number, attention Product Manager
(PM-25), at the following address:

Information Services Section (TS-757C),
Program Management and Support
Division, Office of Pesticide Programs,
Environmental Protection Agency, 401
M St., SW., Washington, D.C. 20460.

In person, bring comments to:
Information Services Section (TS-
757C), Environmental Protection
Agency, Rm. 236, CM#2, 1921
Jefferson Davis Highway, Arlington,
VA 22202.

Information submitted as a comment
concerning this notice may be claimed
confidential by marking any part or all
of that information as "Confidential
Business Information" (CBI).

Information so marked will not be
disclosed except in accordance with
procedures set forth in 40 CFR Part 2. A
copy of the comment that does not
contain CBI must be submitted for
inclusion in the public record.

Information not marked confidential
may be disclosed publicly by EPA
without prior notice. All written
comments filed in response to this
notice will be available for public
inspection in the Information Services

Section office at the address given
above, from 8 a.m. to 4 p.m., Monday
through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT:

By mail: Robert Taylor, (PM-25),
Registration Division (TS-767C),
Environmental Protection Agency,
Office of Pesticide Programs, 401 M
St., SW., Washington, D.C. 20460.
Office location and telephone number:
Rm. 245, CM#2, 1921 Jefferson Davis
Hwy., Arlington, VA 22202, (703-557-
1800).

SUPPLEMENTARY INFORMATION: EPA has
received pesticide (PP), food/feed
additive petitions (FAP) relating to the
establishment of tolerances for certain
pesticide chemicals in or on certain
agricultural commodities.

Initial Filings

1. PP 5F3157 and FAP 5H5446.
Monsanto Co., 1101 17th St., NW,
Washington, D.C. 20036. Proposes to
amend 40 CFR 180.364(a) (raw
agricultural commodities) and 21 CFR
561.253 (feed additive) by establishing
tolerances for the combined residues of
the herbicide glyphosate (N-
(phosphonomethyl)glycine and its
metabolite aminomethylphosphonic acid
resulting from application of the
isopropylamine salt of glyphosate in or
on the following commodities:

Petition ID	CFR affected	Commodities	Parts per million (ppm)
PP 5F3157	40 CFR 180.364	Peanuts	2.0
		Peanut hulls	2.5
FAP 5H5446	21 CFR 561.253	Peanut meal	3.0

The proposed analytical method for
determining residues is high pressure
liquid chromatography (HPLC) with a
fluorescence detector.

2. PP 5F3170. Monsanto Co. Proposes
to amend 40 CFR 180.364(b) by revising
the tolerance expression to read:

Tolerances are established for the
combined residues of glyphosate (N-
(phosphonomethyl)glycine) and its metabolite
aminomethylphosphonic acid resulting from
application of glyphosate isopropylamine salt
for herbicidal and plant growth regulator
purposes or the sodium sesqui salt for growth
regulator purposes in or on the following raw
agricultural commodities:

The tolerance levels for the
commodities listed therein remain the
same.

3. PP 5F3188. E.I. du Pont de Nemours
& Co., Agricultural Chemical Division,
Barley Mill Plaza, Wilmington, DE 19898.
Proposes to amend 40 CFR Part 180 by
establishing tolerances for residues of
the herbicide DPX-F6025 (ethyl 2-[[[4-(4-
chloro-6-methoxypyrimidin-2-yl)amino]-
carbonyl]amino]sulfonyl]benzoate) in
or on soybeans at 0.05 ppm. The
proposed analytical method for
determining residues is HPLC using a
photo-conducting detector.

4. PP 5F3188. Chevron Chemical Co.,
540 Hensley St., Richmond, CA 94804.
Proposes to amend 40 CFR 180.205 by
establishing tolerances for the residues
of the herbicide paraquat (1,1-dimethyl-
4,4'-bipyridinium-ion) derived from
application of either the bis(methyl
sulfate) or the dichloride salt (both
calculated as the cation) in or on rice
grain and straw at 0.05 ppm. The
proposed analytical method for
determining residues is freeing of the
paraquat cation with ammonium
chloride, reduction by sodium dithionite
and determination by
spectrophotometry.

5. FAP 5H3456. Doe Chemical, USA,
P.O. Box 1706, Mullan, MI, 48640.
Proposes to amend 21 CFR 193.350 by
establishing a regulation permitting
residues of the herbicide picloram (4-
amino-3,5,6-trichloropicolinic acid in or
on the palm oil at 0.05 ppm.

6. PP 5F3192. Rhone-Poulenc Inc., 125
Black Horse Lane, Monmouth Junction,
NJ 08852. Proposes to amend 40 CFR
Part 180 by establishing tolerances for
the residues of the herbicide bromoxynil
(3,5-dibromo-4-hydroxybenzonitrile)
resulting from application of its octanoic
acid ester in or on the raw agricultural
commodities, sweet corn and sweet corn
forage, at 0.1 ppm. The proposed
analytical method of determining
residues is gas liquid chromatography.

7. PP 5F3195. Burst AgriTech, 6871, W.
63rd St., Suite 304, Overland Park, KS
66202. Proposes to amend 40 CFR
180.1042 by establishing an exemption
from the requirement of tolerance for the
residues of the plant growth regulator
aqueous extract of seaweed meal
derived from *Laminaria digitata*,
Laminaria hyperborea, *Fucus serratus*,
Ascophyllum nodosum in or on the
commodities alfalfa, barley, beets,
endive, escarole, grape fruit limes, peas,
pecans, popcorn, pumpkin, small grains,
sugarcane, sweet corn, and turnips.

8. PP 5F3213. Platte Chemical Co., P.O.
Box 667, Greeley, CO 80632. Proposes to
amend 40 CFR Part 180 by establishing
an exemption from the requirement of a
tolerance on all crops for the plant
growth regulator cytokinin derived from
cactus.

(Sec. 408(d)(2) 68 Stat. 512, (21 U.S.C.
346a(d)(2)), 409(c)(1), 72 Stat. 1786 (21 U.S.C.
348(c)(1)))

Dated: April 5, 1985.

Robert V. Brown,

Deputy Director, Registration Division, Office
of Pesticide Programs.

[FR Doc. 85-9082 Filed 4-16-85; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION

Applications for Consolidated Hearing

1. The Commission has before it the following mutually exclusive applications for a new FM station:

Applicant, city, and State	File No.	MM Docket No.
A. Stephen G. McGowan d.b.a. McGowan Broad- casting; Mary Esther, FL	BPH-830628AD	85-05
B. Dorothy C. Pennington and William J. Penning- ton, Jr. d.b.a. Golden Sands Broadcasting; Mary Esther, FL	BPH-83070AF	
C. Richard A. Humphrey et al., d.b.a. Mary Esther Broadcasting Company; Mary Esther, FL	BPH-830728AG	
D. Julia N. Frew; Mary Esther, FL	BPH-831026AI	
E. H. French Brown; Mary Esther, FL	BPH-831027AI	
F. Breeze Broadcasting Company, Ltd., a Limited Partnership; Mary Esther, FL	BPH-831027AK	
G. Harry A. Shelter; Mary Esther, FL	BPH-831027AD	
H. Mary Esther Broadcast- ing, Inc.; Mary Esther, FL	BPH-831028AP	
I. Mary Esther Communica- tions, Inc.; Mary Esther, FL	BPH-831028AQ	
J. Marion F. Walker et al., d.b.a. CMW Communica- tions; Mary Esther, FL	BPH-831028AS	
K. Rahe Broadcasting Company, Ltd., a Limited Partnership; Mary Esther, FL	BPH-831028AT	
L. Lulu Two Communica- tions, Inc.; Mary Esther, FL	BPH-831028AW	
M. Clay E. Holladay; Mary Esther, FL	BPH-831028AX	

2. Pursuant to section 309(e) of the Communications Act of 1934, as amended, the above applications have been designated for hearing in a consolidated proceeding upon issues whose hearings are set forth below. The text of each of these issues has been standardized and is set forth in its entirety in a sample standardized Hearing Designation Order (HDO) which can be found at 48 FR 22428, May 18, 1983. The issue headings shown below correspond to issue headings contained in the referenced sample HDO. The letter shown before each applicant's name, above, is used below to signify whether the issue in question applies to that particular applicant.

Issue Heading and Applicant(s)

1. Air Hazard, A, B, D, E, H, I, K, L

2. Ultimate, All

3. Comparative, All

3. If there is any non-standardized issue(s) in this proceeding, the full text of the issue and the applicant(s) to which it applies are set forth in an Appendix to this Notice. A copy of the complete HDO in this proceeding may be obtained by written or telephone request, from the Mass Media Bureau's Contact Representative, Room 242, 1919 M Street, NW., Washington, D.C. 20554. Telephone (202) 632-6334.

W. Jan Gay,

Assistant Chief, Audio Services Division
Mass Media Bureau.

[FR Doc. 85-9253 Filed 4-16-85; 8:45 am]

BILLING CODE 6717-01-M

Hearing Designation Order

Adopted: March 29, 1985.

Released: April 11, 1985.

By the Chief, Video Services Division:

In re Applications of Holiday Group, Limited, Venice Broadcasting Corporation,¹ Santa Rosa Broadcasting, Inc., Venice Communications Limited Partnership, Channel 62 of Venice Limited Partnership, Todd Broadcasting Corporation, Pauline Zlotolow and Associates, Ltd., for construction permit for new television station Venice, FL, MM Docket No. 85-99; File No. BPCT-840507KF; File No. BPCT-840920KF; File No. BPCT-840921KV; File No. BPCT-840921KW; File No. BPCT-840921KX; File No. BPCT-849021KY; File No. BPCT-840921LD (Application Dismissed).

1. The Commission, by the Chief, Video Services Division, acting pursuant to delegated authority, has before it: (a) The above-captioned mutually exclusive applications for authority to construct a new commercial television station on Channel 62, Venice, Florida; (b) a petition to deny filed by Venice Communications Limited Partnership; and (c) related pleadings.²

¹ Venice Broadcasting Corporation filed an amendment on December 21, 1984 after the "B" cut-off date. Since the amendment was required by § 1.65 of the Rules in order to maintain the accuracy and completeness of the application, the amendment will be accepted for § 1.65 purposes only.

² Channel 62 of Venice filed its application on September 21, 1984. (the cut-off date for competing applications), with a facsimile signature. The original signature page was subsequently filed as an amendment on October 29, 1984. It is settled Commission policy that ameliorative amendments may be filed after the "cut-off" date so long as the application was substantially complete when originally filed and the amendment is not the type which would require the assignment of a new file

2. On November 14, 1984, Venice Communications Limited Partnership, (Venice Communications), an applicant for Channel 62, Venice, Florida, filed a petition to deny Pauline Zlotolow and Associates, Ltd.'s competing application. The petitioner alleges that the application is patently defective and should not have been accepted for filing on the grounds that: (a) The applicant failed to submit a seven-and-one-half minute map of its proposed antenna location; and (b) the applicant specified five different sets or coordinates for the antenna site.

3. Zlotolow filed its opposition to the petition to deny on November 27, 1984. Attached to Zlotolow's opposition was an affidavit executed by its technical consultant in which the consultant states that the technical matters raised in the petition resulted from omissions and errors made by his staff during a period when he was unable to prepare or adequately supervise the preparation of the final technical documents due to an illness. After reviewing the application and pleadings in this matter, we do not believe that Zlotolow's application was substantially complete on the "cut-off" date. The coordinates given for the transmitter site are used to determine whether the proposed site meets spacing requirements to other television authorizations, applications and pending rulemaking proceedings, to assure air safety, and to assure that the proposed operation will not affect other radio services. Thus, correct coordinates are an essential part of the processing of an application. We recognize that occasional errors can occur in setting out the coordinates, but we can often understand the correct coordinates by looking at other information in the application. In this case, however, the coordinates given by Zlotolow are inconsistent throughout, the map of the antenna site was missing when filed, the material given to the FAA is also inconsistent, and there is no other map or explanation found within the application, as initially filed, to provide any assurance as to which of the many sites was intended. Thus, the application lacked essential information, could not be processed, and was therefore not substantially complete when filed. Amendments submitted after the cut-off date are permissible in some cases to correct errors and omissions of applications that are

number under § 73.3572(b)(1). See, *Communications Gaithersburg, Inc.*, 60 FCC 2d 537 (1976). Since the Channel 62 of Venice application was complete in all respects, except for an original signature page, on the "cut-off" date, the October 29, 1984 amendment will be accepted for filing.

substantially complete when filed, but amendments filed after the cut-off date to establish substantial completeness cannot be accepted. To hold otherwise would mean that no firm cut-off date exists. See, *Advance, Inc.*, 88 FCC 2d 100 (1981), *recon. denied*, 89 FCC 2d 177 (1982). Accordingly, the application must be dismissed.

4. The effective radiated visual power, antenna height above average terrain and other technical data submitted by each applicant indicate that there would be a significant difference in the size of the area and population which would be served by each. Consequently, the areas and populations which would be within the predicted 64 dBu (Grade B) contour, together with the availability of other television service of Grade B or greater intensity, will be considered under the standard comparative issue, for the purpose of determining whether a comparative preference should accrue to any of the applicants.

5. The Commission is not in receipt of a determination from the Federal Aviation Administration that the tower height and location proposed by each applicant would not constitute a hazard to air navigation. Accordingly, an issue regarding this matter will be specified.

6. In the pending rulemaking proceeding in RM-4861, the Commission proposed to allocate channel 66 to Bradenton, Florida. If that proposal is adopted, the transmitter sites now proposed by Holiday Group Limited (Holiday) and Santa Rosa Broadcasting, Inc. (Santa Rosa) would be 19 miles and 9 miles, respectively, from the reference point of channel 66 in Bradenton, whereas § 73.610 of the Commission's Rules would require a minimum separation of 20 miles. Holiday and Santa Rosa would, therefore, be 1 and 11 miles, respectively, short-spaced. An issue would then be required to determine whether circumstances exist which would warrant a waiver of the rule. In assessing those circumstances, the presiding Administrative Law Judge would consider the fact that the other applicants have specified sites which would comply with the separation requirements. Accordingly, a contingent issue will be specified with respect to each of these proposals. *Delaware Valley Television, Ltd.*, mimeo number 4038, released May 11, 1984 (Channel 48, Burlington, New Jersey).

7. Venice Communications' proposed tower is to be located 1.87 miles from the directional array of AM Station WAMR, Venice, Florida. Because of the proximity of the proposed tower to WAMR, grant of a construction permit to Venice Communications will be conditioned to ensure that WAMR's

radiation pattern is not adversely affected by the construction of the proposed station.

8. Section 73.685(f) of the Commission's Rules requires an applicant proposing to use a directional antenna to include a tabulation of relative field pattern, oriented so that 0° corresponds to True North and tabulated at least every 10° plus any minima or maxima. Channel 62 of Venice Limited Partnership has not supplied this data. Accordingly, the applicant will be required to submit an amendment with the appropriate information to the presiding Administrative Law Judge and a copy each to the Chief, Television Branch, and Chief, Hearing Branch, Mass Media Bureau, within 20 days after this Order is released.

9. Section II, Item 5(a), FCC Form 301, requires that Table I be completed with respect to all parties to the application. Further, § 73.3514(a) of the Commission's Rules requires applicants to provide all information called for by FCC forms, unless the information is inapplicable. However, in *Attribution of Ownership Interests*, 55 R.R. 2d 1464 (1984), the Commission stated that, henceforth, limited partnership interests were not attributable for the purpose of the multiple ownership rules, if the applicant certifies that the limited partnership agreement conforms in all relevant respects to the Uniform Limited Partnership Act (ULPA) and "if the limited partner is not involved in any material respect in the business or operation of the station." *Id.* at 1485. Further, the Commission directed that Form 301, among others, be amended to conform to the new attribution standards. *Id.* at 1493. Although changes in the form have not yet been made, there is now no need to provide information as to the limited partners if an applicant can submit the necessary certification. If the certification is not appropriate, of course, the limited partners would be considered to have attributable interests, and the necessary information as to them would have to be filed as an amendment. Further, the Commission retained the cross-interest policy as to other attributable media interests in the same area. *Id.* at 1490. Channel 62 Limited Partnership has certified that its limited partnership agreement conforms in all respects to the ULPA. It has further certified that the limited partner has no other media interest subject to the cross-interest policy. However, the applicant did not certify that the limited partner is not involved in any material respect in the operation of the station. Accordingly, Channel 62 of Venice Limited will be

required to submit a statement with respect to its limited partner's involvement in the business or operation of the station.

11. Except as indicated by the issues specified below, the applicants are qualified to construct and operate as proposed. Since these applications are mutually exclusive, the Commission is unable to make the statutory finding that their grant would serve the public interest, convenience, and necessity. Therefore, the applications must be designated for hearing in a consolidated proceeding on the issues specified below.

12. Accordingly, it is ordered, that pursuant to section 309(e) of the Communications Act of 1934, as amended, the applications are designated for hearing in a consolidated proceeding, to be held before an Administrative Law Judge at a time and place to be specified in a subsequent Order, upon the following issues:

1. To determine with respect to each of the applicants, whether there is a reasonable possibility that the tower height and location proposed by each would constitute a hazard to air navigation.

2. In the event that the Commission adopts the pending rule making proposal in RM-4861 and allocates channel 66 to Bradenton, Florida, to determine whether the application of Holiday Group Limited and the application of Santa Rosa Broadcasting, Inc., would be consistent with § 73.610 of the Commission's Rules and, if not, whether circumstances exist which would warrant a waiver of the rule.

3. To determine which of the proposals would, on a comparative basis, best serve the public interest.

4. To determine, in light of the evidence adduced pursuant to the foregoing issues, which of the applications should be granted.

13. It is further ordered, that, Channel 62 of Venice Limited Partnership, shall amend its application to furnish the information required by Paragraph 9 of this Order, within 20 days after this Order is released.

14. It is further ordered that, Channel 62 of Venice Limited Partnership shall submit an amendment providing the information required by § 73.685(f) of the Commission's Rules, to the presiding Administrative Law Judge and a copy each to the Chief, Television Branch, and Chief, Hearing Branch, Mass Media Bureau, within 20 days after this Order is released.

15. It is further ordered, that, in the event of a grant of the application of Venice Communications Limited

Partnership, the construction permit shall be conditioned as follows:

Prior to construction of the tower authorized herein, permittee shall notify AM Station WAMR, Venice, Florida, so that, if necessary, the AM station may determine operating power by the indirect method and request temporary authority from the Commission in Washington, D.C. to operate with parameters at variance in order to maintain monitoring point field strengths within authorized limits. Permittee shall be responsible for the installation and continued maintenance of detuning apparatus necessary to prevent adverse effects upon the radiation pattern of the AM station. Both prior to construction of the tower and subsequent to the installation of all appurtenances thereon, a partial proof of performance, as defined by § 73.154(a) of the Commission's Rules, shall be conducted to establish that the AM array has not been adversely affected and, prior to or simultaneous with the filing of the application for license to cover this permit, the results submitted to the Commission.

16. It is further ordered, that the amendment filed by Channel 62 of Venice on October 29, 1984, is accepted for filing.

17. It is further ordered, that the Petition to Deny filed by Venice Communications Limited Partnership is granted, and the application filed by Pauline Zlotolow and Associates, Ltd. is dismissed.

18. It is further ordered, that the petition for leave to amend filed by Venice Broadcasting Corporation on December 21, 1984, is hereby granted and the amendment filed on the same date is hereby accepted for filing for 1.65 purposes only.

19. It is further ordered, that the Federal Aviation Administration is made a party respondent to this proceeding with respect to issue 1.

20. It is further ordered, that to avail themselves of the opportunity to be heard, the applicants and the party respondent herein shall, pursuant to § 1.221(c) of the Commission's Rules, in person or by attorney, within 20 days of the mailing of this Order, file with the Commission, in triplicate, a written appearance stating an intention to appear on the date fixed for the hearing and present evidence on the issues specified in this Order.

21. It is further ordered, that the applicants herein shall, pursuant to section 311(a)(2) of the Communications Act of 1934, as amended, and § 73.3594 of the Commission's Rules, give notice of the hearing within the time and in the manner prescribed in such Rule, and shall advise the Commission of the publication of such notice as required by § 73.3594(g) of the Rules.

Federal Communications Commission.

Roy J. Stewart,

Chief, Video Services Division, Mass Media Bureau.

[FR Doc. 85-9251 Filed 4-16-85; 8:45 am]

BILLING CODE 6717-01-M

Hearing Designation Order

Adopted: March 29, 1985.

Released: April 11, 1985.

By the Chief, Video Services Division:

In re Applications of Wise County Messenger, Inc., Karen L. Hicks, Chavala Broadcasting, Inc., for construction permit Decatur, Texas, MM Docket No. 85-100; File No. BPCT-841026KE; File No. BPCT-850107KG; File No. BPCT-850108KK.

1. The Commission, by the Chief, Video Services Division, acting pursuant to delegated authority, has before it the above-captioned mutually exclusive applications for a new commercial television station to operate on Channel 29, Decatur, Texas.¹

2. The effective radiated visual power, antenna height above average terrain and other technical data submitted by the applicants indicate that there would be a significant difference in the size of the area and population that each proposes to serve. Consequently, the areas and populations which would be within the predicted 64 dBu (Grade B) contour, together with the availability of other television service of Grade B or greater intensity, will be considered under the standard comparative issue, for the purpose of determining whether a comparative preference should accrue to any of the applicants.

3. No determination has been reached that the tower height and location proposed by each of the applicants would not constitute a hazard to air navigation. Accordingly, an issue regarding this matter will be specified.

4. Karen L. Hicks did not certify her financial qualifications, but she indicated that certification would be forthcoming. Ms. Hicks will be given 20 days from the release date of this Order to review her financial proposal in light of Commission requirements, to make any changes that may be necessary, and, if appropriate, to submit a certification to the Administrative Law

¹ Chevala Broadcasting, Inc., states in its application that Mr. Raul Tapia, its President, will divest certain broadcast interests within a period to be specified by the Commission, if such a divestiture "is decisionally significant." All broadcast interests are decisionally significant in the comparative process. The decision to divest, until the end of the period when amendments can be made as a matter of right, is for the applicant to make, not the Commission. The applicant did not make an election in this case, and it cannot now upgrade its comparative posture.

Judge in the manner called for in section III, FCC Form 301, as to her financial qualifications. If Ms. Hicks cannot make the required certification, she shall so advise the Administrative Law Judge who shall then specify an appropriate issue. *Minority Broadcasters of East St. Louis, Inc.*, BC Docket No. 82-378 (released July 15, 1982).

5. Except as indicated by the issues specified below, the applicants are qualified to construct and operate as proposed. Since the applications are mutually exclusive, the Commission is unable to make the statutory finding that their grant would serve the public interest, convenience, and necessity. Therefore, the applications must be designated for hearing in a consolidated proceeding on the issues specified below.

6. Accordingly, it is ordered, that pursuant to section 309(e) of the Communications Act of 1934, as amended, the applications are designated for hearing in a consolidated proceeding, to be held before an Administrative Law Judge at a time and place to be specified in a subsequent Order, upon the following issues:

1. To determine, with respect to each of the applicants, whether the tower height and location proposed by each would constitute a hazard to air navigation.

2. To determine which of the proposals would, on a comparative basis, best serve the public interest.

3. To determine, in light of the evidence adduced pursuant to the foregoing issues, which of the applications should be granted.

7. It is further ordered, that the Federal Aviation Administration is made a party respondent with respect to issue 1.

8. It is further ordered, that Karen L. Hicks shall, within 20 days after this order is released, submit a financial certification in the form required by section III, FCC Form 301, or advise the Administrative Law Judge that the certification cannot be made, as may be appropriate.

9. It is further ordered, that to avail themselves of the opportunity to be heard, the applicants and the party respondent herein shall, pursuant to § 1.221(c) of the Commission's Rules, in person or by attorney, within 20 days of the mailing of this Order, file with the Commission, in triplicate, a written appearance stating an intention to appear on the date fixed for the hearing and present evidence on the issues specified in this order.

10. It is further ordered, that the applicants herein shall, pursuant to

section 311(a)(2) of the Communications Act of 1934, as amended, and § 73.3594 of the Commission's Rules, give notice of the hearing within the time and in the manner prescribed in such Rule, and shall advise the Commission of the publication of such notice as required by § 73.3594(g) of the Rules.

Federal Communications Commission.

Roy J. Stewart,

Chief, Video Services Division, Mass Media Bureau.

[FR Doc. 85-9252 Filed 4-16-85; 8:45 am]

BILLING CODE 6717-01-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

Agency Information Collection Submitted to the Office of Management and Budget for Clearance

The Federal Emergency Management Agency (FEMA) has submitted to the Office of Management and Budget the following information collection package for clearance in accordance with the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Type: Extension of 3067-0026.

Title: Application for Loan Cancellation.

Abstract: The form was developed for use by local governments in conjunction with the community Disaster Loan Program (Section 414, Pub. L. 93-288). The form was utilized to request cancellation of a Community Disaster Loan in accordance with the provisions of the law and regulations pertaining to Community Disaster Loans.

Type of Respondents: State or Local Governments.

Number of Respondents: 5.

Burden Hours: 30.

Copies of the above information collection request and supporting documentation can be obtained by calling or writing the FEMA Clearance Officer, Linda Shiley, (202) 287-9906 500 C. Street, SW., Washington, D.C. 20472.

Comments should be directed to Mike Weinstein, Desk Officer for FEMA, Office of Laboratories and Regulatory Affairs, OMB, Rm. 3235, New Executive Office Building, Washington, D.C. 20503.

Dated: April 10, 1985.

Walter A. Girstantas,

Director, Administrative Support.

[FR Doc. 85-9183 Filed 4-16-85; 8:45 am]

BILLING CODE 6718-01-M

Agency Information Collection Submitted to the Office of Management and Budget for Clearance

The Federal Emergency Management Agency (FEMA) has submitted to the Office of Management and Budget the following information collection package for clearance in accordance with the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Type: Extension of 3067-0034.

Title: Application for Community Disaster Loan.

Abstract: The Community Disaster Loan Program an aspect of the Disaster Relief Act of 1974, Pub. L. 93-288, offers loans to disaster affected local governments with the possibility that all or part of the loan could be cancelled. Basic Authorities are contained in section 414, PL 93-288 and Federal Regulation 44 CFR 205 subpart F.

Type of Respondents: State or Local Governments.

Number of Respondents: 5.

Burden Hours: 30.

Copies of the above information collection request and supporting documentation can be obtained by calling or writing the FEMA Clearance Officer, Linda Shiley, (202) 287-9906, 500 C. Street, SW., Washington, D.C. 20472.

Comments should be directed to Mike Weinstein, Desk Officer for FEMA, Office of Information and Regulatory Affairs, OMB, Rm. 3235, New Executive Office Building, Washington, D.C. 20503.

Dated: April 10, 1985.

Walter A. Girstantas,

Director, Administrative Support.

[FR Doc. 85-9184 Filed 4-16-85; 8:45 am]

BILLING CODE 6718-01-M

FEDERAL HOME LOAN BANK BOARD

Federal Savings and Loan Advisory Council; Public Meeting

Correction

FR Doc. 85-9052 which announced a meeting on April 25, 1985, of the Federal Savings and Loan Advisory Council was published in the issue of Monday, April 15, 1985, on page 14791 in the section of the issue reserved for Sunshine Act meetings. It should have been published in the Notices section of the issue.

BILLING CODE 1505-02-M

FEDERAL MARITIME COMMISSION

[Docket No. 85-11]

Armada Great Lakes/East Africa Service, Ltd. and Great Lakes Transcaribbean Line; Order of Investigation and Hearing

Armada Great Lakes/East Africa Service Ltd. (Armada/East Africa) and Great Lakes Transcaribbean Line (GLTL) are common carriers in United States foreign commerce.

The above named carriers appear to have been implementing a joint service agreement continuously from 1981 until October 20, 1984, despite its being unapproved and not legally effective. The joint service operates under the name Armada/GLTL East Africa Service (Armada/GLTL Line). In early 1983 this came to the attention of the Commission and the agreement parties were informed that their agreement was subject to the filing and approval requirements of section 15, Shipping Act, 1916, 46 U.S.C. 814, which was then in effect. Although Armada/East Africa and GLTL immediately filed an agreement, they continued to implement their agreement without benefit of Commission approval. In order to resolve doubts which had been raised by the parties concerning Commission jurisdiction over the agreement (No. 10464), Docket No. 83-39, *Armada/GLTL East Africa Service (Agreement No. 10464)* was instituted on September 9, 1983. The sole issue in that proceeding was whether the Commission had jurisdiction over the agreement referred to above. On November 23, 1983, after full participation by the agreement parties, the Administrative Law Judge served his Initial Decision, finding jurisdiction. There were no exceptions filed and the decision became administratively final on January 5, 1984. Although the parties initiated discussions with Commission staff regarding the approval of their agreement, they nevertheless continued its implementation. This continued despite warnings from Commission staff that to do so was unlawful and at the parties' peril. On April 12, 1984, the parties filed an amended agreement which, like the original version, was protested. On June 13, 1984, the Commission returned the agreement to the parties as unapprovable, noting that it had not been processed to completion prior to the effective date of the Shipping Act, 1984. Armada/East Africa and GLTL subsequently filed an amended agreement on September 5,

1984, which was designated No. 207-010640 and became effective on October 20, 1984.

Because the parties continually implemented their joint service agreement during the time outlined above despite its being unapproved and not legally effective, the Commission's Bureau of Hearing Counsel, after consultation with the Commission, asserted a claim for civil penalties against both. At no point has either party denied implementing the agreement or that such implementation constitutes a violation. Because a satisfactory compromise of the subject claims could not be reached, the Commission has decided to institute this proceeding to determine and assess the appropriate penalty for the violations referred to above.

Therefore, it is ordered That, pursuant to section 22 of the Shipping Act, 1916 (46 U.S.C. app. 831) and section II of the Shipping Act of 1984 (46 U.S.C. app. 1710), a formal investigation and hearing is instituted to determine:

1. Whether Armada Great Lakes/East Africa Service, Ltd. and Great Lakes Transcaribbean Line violated section 15, Shipping Act, 1916 (46 U.S.C. app. 814) and section 10 of the Shipping Act of 1984 (46 U.S.C. app. 1709) by implementing Agreement No. 207-010640 prior to its lawful effective date¹;

2. Whether, in the event that Armada Great Lakes/East Africa Service Ltd. and/or Great Lakes Transcaribbean Line are found to have violated section 15, Shipping Act, 1916 and/or section 10 of the Shipping Act of 1984, either or both should be assessed penalties and, if so, the appropriate level of penalty;

It is further ordered That Armada Great Lakes/East Africa Service Ltd. and Great Lakes Transcaribbean Line be named Respondents in this proceeding;

It is further ordered That a public hearing be held in this proceeding and that the matter be assigned for hearing and decision by an Administrative Law Judge of the Commission's Office of Administrative Law Judges at a date and place to be hereafter determined by the Presiding Administrative Law Judge. The hearing shall include oral testimony and cross-examination in the discretion of the Presiding Administrative Law Judge only upon a proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents, or that the nature of the matters in issue is such that an oral hearing and cross-

examination are necessary for the development of an adequate record;

It is further ordered That, pursuant to the terms of Rule 61 of the Commission's Rules of Practice and Procedure (46 CFR 502.61), the initial decision of the presiding officer in this proceeding shall be issued by April 14, 1986, and the final decision of the Commission shall be issued by August 14, 1986;

It is further ordered That notice of this Order be published in the *Federal Register*, and a copy thereof be served upon the Respondents and the Commission's Bureau of Hearing Counsel;

It is further ordered That, in accordance with Rule 42 of the Commission's Rules of Practices and Procedure (46 CFR 502.42), the Commission's Bureau of Hearing Counsel shall be a party to this proceeding;

It is further ordered That other persons having an interest in participating in this proceeding may file petitions for leave to intervene in accordance with Rule 72 of the Commission's Rules of Practice and Procedure (46 CFR 502.72);

It is further ordered That all future notices, orders, or decisions issued in this proceeding, including notice of the time and place of hearing or prehearing conference, shall be mailed directly to all parties of record; and

It is further ordered that all documents submitted by any party of record in this proceeding shall be directed to the Secretary, Federal Maritime Commission, Washington, D.C. 20573, in accordance with Rule 118 of the Commission's Rules of Practice and Procedure (46 CFR 502.118), as well as being mailed directly to all parties of record.

Bruce A. Dombrowski,
Acting Secretary.

Appendix A

The following is a partial list of advertisements by which Armada/GLTL East Africa Service held out to provide common carrier service. Parenthetical listings refer to illustrative voyage confirmations in Lloyd's Voyage Record, Journal of Commerce:

April 29, 1981, Page 32
June 15, 1981, Page 20-B
August 17, 1981, Page 20-B
October 15, 1981, Page 20-B
December 15, 1981, Page 20-B
February 16, 1982, Page 20-B
April 15, 1982, Page 20-B
June 15, 1982, Page 20-B
August 16, 1982, Page 20-B
October 15, 1982, Page 20-B
December 15, 1982, Page 20-B
January 14, 1983, Page 20-B

January 14, 1983, Page 5-B
January 14, 1983, Page 15-B
February 15, 1983, Page 20-B
March 15, 1983, Page 20-B
April 15, 1983, Page 20-B
May 16, 1983, Page 20-B
June 15, 1983, Page 20-B
July 15, 1983, Page 20-B
August 15, 1983, Page 20-B
September 15, 1983, Page 20-B
October 14, 1983, Page 20-B
November 15, 1983, Page 20-B
December 15, 1983, Page 20-B
December 20, 1983, Page 5-B
December 20, 1983, Page 15-B
January 10, 1984, Page 20-B
January 10, 1984, Page 5-B
January 10, 1984, Page 15-B
January 20, 1984, Page 20-B
January 20, 1984, Page 5-B
January 20, 1984, Page 15-B
February 10, 1984, Page 20-B
February 10, 1984, Page 5-B
February 10, 1984, Page 15-B
February 21, 1984, Page 20-B
February 21, 1984, Page 15-B
March 9, 1984, Page 20-B
(NAXOS ISLAND, May 29, 1984, Page 156)
March 20, 1984, Page 20-B
April 10, 1984, Page 20-B
(HEROINAE, July 24, 1984, Page 95)
May 10, 1984, Page 20-B
(SHENANDOAH, June 12, 1984, Page 205)
May 21, 1984, Page 20-B
(OCEANIS, August 7, 1984, Page 164)
June 11, 1984, Page 20-B
June 20, 1984, Page 20-B
(REGIN A, August 7, 1984, Page 186)
July 10, 1984, Page 20-B
July 20, 1984, Page 20-B
(WILHELM SCHULTE, August 21, 1984, Page 242)
August 10, 1984, Page 20-B
August 20, 1984, Page 20-B
(RENATE SCHULTE, September 25, 1984, Page 187)
September 10, 1984, Page 20-B
September 20, 1984, Page 20-B
(HEROINAE, November 13, 1984, Page 95)
October 10, 1984, Page 20-B
October 19, 1984, Page 20-B
(G HIK AS, November 27, 1984, Page 84)

Illustrative advertisements for land-bridge service from the U.S. West Coast can be found in:

Pacific Shipper, February 14, 1983, Page 52
Pacific Shipper, April 23, 1984, Page 52
[FR Doc. 85-9189 Filed 4-16-85; 8:45 am]
BILLING CODE 8730-01-M

Agreement(s) Filed

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, D.C. Office of the Federal Maritime Commission, 1100 L Street, NW., Room 10325. Interested parties may submit comments on each

¹ Appendix A is a partial list of advertisements by which the parties held out to perform common carriage through their joint service.

agreement to the Secretary, Federal Maritime Commission, Washington, D.C. 20573, within 10 days after the date of the Federal Register in which this notice appears. The requirements for comments are found in § 572.603 of Title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 224-004079-001.

Title: Oakland Terminal Agreement.

Parties:

The Port of Oakland (Port)

Westwood Shipping Lines

(Westwood)

Synopsis: This agreement modifies the basic agreement between the Port and Westwood whereby the Port assigns certain marine terminal facilities in the Port's Outer Harbor Terminal, Berth 6 to Westwood. The amendment provides for the suspension of the operation of the agreement during the period in which Westwood transfers its operations to the facility preferentially assigned by the Port to American President Lines (APL), and uses said APL assigned facility as it published regularly scheduled Northern California port of call. It provides for the extension of the term of the agreement to and including March 31, 1990, with an option to extend the agreement for an additional two year period.

Agreement No.: 221-010619-001.

Title: Oakland Terminal Agreement.

Parties:

The Port of Oakland (Port)

East Asiatic Co., Ltd. (EAC)

Synopsis: This agreement modifies the basic agreement between the parties whereby the Port assigns certain marine terminal facilities in the Port's Charles Howard Terminal to EAC. The amendment provides that provisions of the agreement with respect to User's payment of dockage and wharfage shall apply to User's vessels and cargo handled to Mitsui O.S.K. Lines' assigned Port of Oakland Public Container Terminal as a result of User's FMC approved Joint Service Agreement with Mitsui O.S.K. Line.

Agreement No.: 224-010744.

Title: Oakland Terminal Agreement.

Parties:

The Port of Oakland (Port)

Mitsui O.S.K. Lines, Ltd. (Mitsui)

Synopsis: Agreement No 224-010744 between the Port and Mitsui is a terminal use agreement providing that Mitsui shall have the nonexclusive right to assigned premises at the Port's Outer Harbor Terminal, Berth 6, for the handling of its vessels and related operations in its transpacific container service. Mitsui will have the right to

transfer its rights and obligations under the agreement to other of the Port's public container terminals. Mitsui agrees that the assigned premises shall be its published Northern California port of call. As a consideration Mitsui shall pay to the Port 90 percent of the tariff dockage and wharfage revenues, instead of 100 percent. If Mitsui's usage generates in excess of 31,000 revenue tons in a contract year, wharfage payment for such tonnage in excess of that amount will be refunded to Mitsui. The term of the agreement commences upon the first of the month following the determination of effectiveness by the Commission and terminates March 31, 1990.

Agreement No.: 231-010745.

Title: Duluth-Superior Terminal Agreement.

Parties:

Meehan Seaway Service, Inc.—

Superior, Wisconsin

Seaway Port Authority—Duluth,

Minnesota

Synopsis: This agreement will permit marine terminal operators in the adjacent ports of Superior and Duluth to discuss and establish terminal rates, charges, classifications, rules, regulations and practices applicable to and governing the use and operation of marine terminal facilities at Superior and Duluth. Any agreed upon rates shall be published in a tariff on file with the Commission. Any party may withdraw from the agreement or take independent action upon giving 30 days' notice to the other party.

Agreement No.: 217-010746.

Title: Columbus/Pace Cross Charter Agreement.

Parties:

Columbus Line

Pace Line

Synopsis: The proposed agreement would establish a space chartering arrangement between the parties in the trade between ports on the Atlantic and Gulf Coasts of the United States, Puerto Rico, the Virgin Islands, American Samoa and Eastern Canada and inland and coastal points via such ports and ports and inland and coastal points in Australia, New Zealand, Eastern Canada, Cook Islands, Fiji, New Caledonia, Vanuatu, Western Samoa, Solomon Islands, Society Islands, Tonga, Kiribati, Tuvalu and Papua New Guinea. It would permit the parties to charter space on each other's vessels and share terminal facilities and equipment.

Dated: April 12, 1985.

By order of the Federal Maritime Commission.

Bruce A. Dombrowski,

Acting Secretary.

[FR Doc. 85-9269 Filed 4-16-85; 8:45 am]

BILLING CODE 6730-01-M

[Agreement No. 224-002813-004]

Agreement Between the Port of San Francisco (Port) and California Stevedore and Ballast Company (CS&B); Erratum

The Federal Register Notice published on March 15, 1985, (Vol. 50, No. 51, Pg. 10543) incorrectly described the title of Agreement No. 224-002813 as "The Port of San Francisco (Port), California Stevedore and Ballast Company (CS&B), "whereas it should have been shown as "San Francisco Terminal Agreement".

Dated: April 12, 1985.

By Order of the Federal Maritime Commission

Bruce A. Dombrowski,

Acting Secretary.

[FR Doc. 85-9270 Filed 4-16-85; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

Bank of Boston Corp. et al.; Applications To Engage de Novo in Permissible Nonbanking Activities

The companies listed in this notice have filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such

as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the Offices of the Board of Governors not later than May 7, 1985.

A. Federal Reserve Bank of Boston (Richard E. Randall, Vice President) 600 Atlantic Avenue, Boston, Massachusetts 02106:

1. *Bank of Boston Corporation*, Boston, Massachusetts; to expand *de novo* its data processing and management consulting services, nationwide, through its subsidiary BancBoston FBC Inc., Boston, Massachusetts.

B. Federal Reserve Bank of Chicago (Franklin D. Dreyer, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *First Interstate Corporation of Wisconsin*, Sheboygan, Wisconsin; to engage *de novo* through its subsidiary, First Interstate Trust Company of Wisconsin, Sheboygan, Wisconsin, in providing securities brokerage services, related securities credit activities pursuant to the Board's Regulation T, and incidental activities such as offering custodial services, individual retirement accounts, and cash management accounts. Such securities brokerage services are to be restricted to buying and selling securities solely for the account of customers and will not include securities underwriting or dealing, or investment advice or research services.

Board of Governors of the Federal Reserve System, April 11, 1985.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 85-9177 Filed 4-16-85; 8:45 am]

BILLING CODE 6210-01-M

DuPage Financial Corp. et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12

CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than May 10, 1985.

A. Federal Reserve Bank of Chicago (Franklin D. Dreyer, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *DuPage Financial Corporation*, Lake Forest, Illinois; to become a bank holding company by acquiring 100 percent of the voting shares of Washington Bank and Trust Company of Naperville, Naperville, Illinois.

B. Federal Reserve Bank of San Francisco (Harry W. Green, Vice President) 101 Market Street, San Francisco, California 94105:

1. *Ventura County National Bancorp.*, Oxnard, California; to acquire 50.1 percent of the voting shares of Camarillo Community Bank, Camarillo, California.

Board of Governors of the Federal Reserve System, April 11, 1985.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 85-9178 Filed 4-16-85; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control

**Cooperative Agreement for a Project
to Study Approach to Health
Promotion Consistent with 1990 Health
Promotion/ Disease Prevention,
Objectives for the Nation; Availability
of Funds for Fiscal Year 1985**

The Centers for Disease Control announces the availability of funds in Fiscal Year 1985 for a cooperative agreement with Emory University

School of Medicine, Department of Community Medicine (EUSM/DCM), to conduct a demonstration project. The EUSM/DCM will study an approach to health promotion in an underserved, predominantly low income, black community which has existing hypertension and nutrition problems in an endeavor to improve the health status, help reduce risk factors, and increase public awareness of the health problems that exist in this community. Catalog of Federal Domestic Assistance Number 13.183. This program is authorized under section 301(a) of the Public Health Service Act (42 U.S.C. 241(a)), as amended.

Assistance will be provided only to the Emory University School of Medicine, Department of Community Medicine, for this project. The EUSM/DCM has a long-standing and distinguished record of community service to the needy in Georgia. This record is marked by ongoing communication and collaboration with the State department of health and county health departments. With structures in the Kirkwood Community that are already in place—a citizens advisory group from that community, workers in the DeKalb-Grady Clinic (i.e. EUSM/DCM, DeKalb County Health Department, Grady Hospital) and services already being delivered to the citizens of Kirkwood by EUSM/DCM with the DeKalb Grady Clinic and through Grady Hospital—EUSM/DCM is the only institution that has access to the information necessary to carry out this project. Therefore, this is not a formal request for applications. It is expected that approximately \$103,000 will be available during Fiscal Year 1985 to support this project. It is anticipated that the cooperative agreement will be funded for an initial budget period of 12 months with a 3-year project period. Continuation awards will be made on the basis of satisfactory progress in meeting project objectives and on the availability of funds. Funding estimates outlined above may vary and are subject to change.

Information may be obtained from Leo A. Sanders, Chief, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, N.E., Room 321, Atlanta, Georgia 30305, telephone (404) 262-6575 or FTS 236-6575.

Dated: April 5, 1985.

William E. Muldoon,

Director, Office of Program Support, Centers for Disease Control.

[FR Doc. 85-9205 Filed 4-16-85; 8:45 am]

BILLING CODE 4160-18-M

Food and Drug Administration

[Docket No. 84N-0067; DESI No. 10826]

Certain Drugs Containing Antibiotic, Corticosteroid, and Antifungal Components; Reevaluation

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) (1) classifies combination products containing triamcinolone acetonide and nystatin in cream and ointment form as effective for the treatment of cutaneous candidiasis, and (2) announces the conditions for their approval and marketing.

DATE: Supplements due on or before June 17, 1985.

ADDRESSES: Communications in response to this notice should be identified with reference number DESI 10826, directed to the attention of the appropriate office named below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Supplements to full new drug applications (identify with NDA number): Division of Anti-Infective Drug Products (HFN-815), Center for Drugs and Biologics.

Original abbreviated new drug applications and supplements thereto (identify as such): Division of Generic Drug Monographs (HFN-230), Center for Drugs and Biologics.

Requests for an opinion of the applicability of this notice to a specific product: Division of Drug Labeling Compliance (HFN-310), Center for Drugs and Biologics.

FOR FURTHER INFORMATION CONTACT: Herbert Gerstenzang, Center for Drugs and Biologics (HFN-360), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: In response to Federal Register notices of June 29, 1972 (37 FR 12856); October 9, 1974 (39 FR 36365); and September 25, 1981 (46 FR 47408), E.R. Squibb & Sons, Inc., submitted data to demonstrate the effectiveness of Mycolog Cream and Ointment, which contain triamcinolone acetonide, nystatin, neomycin sulfate, and gramicidin. On October 20, 1981, Squibb requested a hearing on FDA's proposal in the September 1981 Federal Register notice to withdraw approval of the drug products. FDA's proposal was based on its finding that the four-ingredient products were lacking in substantial evidence of effectiveness. A notice of hearing was published on September 17, 1984 (49 FR 36439).

Squibb has proposed to reformulate the Mycolog products to contain only triamcinolone acetonide and nystatin. The agency has evaluated Squibb's data, including an unpublished, large multicenter study, on the four-ingredient combinations to determine whether there is substantial evidence of effectiveness of the proposed two-ingredient combinations. Specifically, the agency addressed the question whether the proposed triamcinolone acetonide-nystatin combinations provide earlier relief of signs and symptoms than the antifungal ingredient (nystatin) alone, for the treatment of cutaneous candidiasis. FDA has determined that there is substantial evidence that the proposed two-ingredient products provide a significant improvement in the clinical severity of cutaneous candidiasis during the first few days of treatment.

Accordingly, the Director of the Center for Drugs and Biologics classifies the drug products listed below as effective for the treatment of cutaneous candidiasis. The original formulations of these drug products are still the subject of a pending hearing and will be addressed at a later time.

1. The part of NDA 60-572 pertaining to the ointment preparation containing triamcinolone acetonide 0.1 percent and nystatin 100,000 units/g; E.R. Squibb & Sons, Inc., P.O. Box 4000, Princeton, NJ 08540; and

2. The part of NDA 60-576 pertaining to the cream preparation containing triamcinolone acetonide 0.1 percent and nystatin 100,000 units/gram (g).

These drugs are regarded as new drugs (21 U.S.C. 321(p)). Supplemental new drug applications are required to revise the labeling in and to update previously approved applications providing for the drugs. An approved new drug application is a requirement for marketing the drug products.

In addition to the holder of the applications specifically named above, this notice applies to any person who manufactures or distributes a drug product that is not the subject of an approved new drug application and that is identical to a drug product named above. It may also be applicable, under 21 CFR 310.6, to a related or similar drug product that is not the subject of an approved new drug application. It is the responsibility of every drug manufacturer or distributor to review this notice to determine whether it covers any drug product that the person manufactures or distributes. Any person may request an opinion of the applicability of this notice to a specific drug product by writing to the Division of Drug Labeling Compliance (address above).

A. Effectiveness Classification.

FDA has reviewed all available evidence and concludes that the drug products are effective for the indication in the labeling conditions below.

B. Conditions for Approval and Marketing.

FDA is prepared to approve abbreviated new drug applications and supplements to previously approved new drug applications under conditions described herein.

1. *Form of drug.* These preparations are in cream or ointment form suitable for topical administration.

2. *Labeling conditions.* a. The label bears the statement, "Caution: Federal law prohibits dispersing without prescription."

b. The drug is labeled to comply with all requirements of the act and regulations, and the labeling bears adequate information for safe and effective use of the drug. The indication is as follows:

For the treatment of cutaneous candidiasis: it has been demonstrated that the nystatin-steroid combination provides greater benefit than the nystatin component alone during the first few days of treatment.

3. *Marketing status.* a. Marketing of a drug product that is now the subject of an approved or effective new drug application may be continued provided that on or before June 17, 1985, the holder of the application has submitted (i) a supplement for revised labeling as needed to be in accord with the labeling conditions described in this notice, and complete container labeling if current container labeling has not been submitted, and (ii) a supplement to provide updating information with respect to items 6 (components), 7 (composition), and 8 (methods, facilities, and controls) of new drug application form FD-356H (21 CFR 314.1(c)).

b. Approval of an abbreviated new drug application (21 CFR 314.1) must be obtained before marketing these products. The requirements for bioavailability testing are waived for topically applied preparations (21 CFR 320.22). Marketing the drug products before approval of a new drug application will subject those products, and those persons who caused the products to be marketed, to regulatory action.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 507, 52 Stat. 1050-1053, as amended, 59 Stat. 463 as amended (21 U.S.C. 352, 355, 357)) and under authority delegated to the Director of the Center for Drugs and Biologics (21 CFR 5.70 and 5.82).

Dated: April 9, 1985.

Harry M. Mayer, Jr.,

Director, Center for Drugs and Biologics.

[FR Doc. 85-9175 Filed 4-16-85; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 80N-0012, DESI 10826]

Drugs for Human Use; Drug Efficacy Study Implementation; Certain Topical Anti-Infective Drug Products; Cortisporin Cream; Amended Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) amends a notice of opportunity for hearing that proposed to withdraw approval of the entire new drug application (NDA) for Cortisporin Cream, a topical antibiotic combination drug product containing neomycin sulfate, polymyxin B sulfate, gramicidin, and hydrocortisone. As amended, the proposal applies to the NDA only as it pertains to the old formulation of the product. FDA also announces the conditions for marketing the reformulated and renamed product for the indication for which it is regarded as effective.

EFFECTIVE DATE: April 17, 1985.

ADDRESSES: Communications in response to this notice should be identified with reference number DESI 10826, and directed to the attention of the appropriate office named below.

Original abbreviated new drug applications (original antibiotic Form 6's) and supplements thereto (identify as such): Division of Generic Drug Monographs (HFN-230), Center for Drugs and Biologics, 5600 Fishers Lane, Rockville, MD 20857.

Requests for an opinion of the applicability of this notice to a specific product: Division of Drug Labeling Compliance (HFN-310), Center for Drugs and Biologics, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Judy O'Neal, Center for Drugs and Biologics (HFN-366), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: In a notice published in the *Federal Register* of September 25, 1981 (46 FR 47408), the Director of the Bureau of Drugs (now the Center for Drugs and Biologics) reclassified certain topical anti-infective drug products for dermatologic use to lacking substantial evidence of effectiveness proposed to withdraw approval of the new drug applications for those products in their entirety, and

offered an opportunity for a hearing on the proposal.

Among the products identified in the September 1981 notice for which hearing requests were submitted was:

NDA 50-218; Cortisporin Cream containing neomycin sulfate EQ 3.5 milligram (mg) base/gram (gm), polymyxin B sulfate 10,000 units, gramicidin .25 mg, and hydrocortisone 0.5 percent; Burroughs Wellcome Co., Inc., 3030 Cornwallis Rd., Research Triangle Park, NC 27749.

Burroughs Wellcome has supplemented NDA 50-218 to provide for a reformulation that deletes gramicidin from the formulation above.

The hearing request on the gramicidin-containing formulation is still pending. This product will be the subject of a future *Federal Register* notice.

(Final rules amending the antibiotic drug regulations have exempted antibiotic-containing drugs for dermatologic use (45 FR 71354, October 28, 1980) and, later, all classes of antibiotic-containing drugs (47 FR 39155, September 7, 1982) from certification requirements. Under these provisions, approved antibiotic Form 5's and Form 6's are regarded as new drug applications (NDA's) and abbreviated new drug applications (ANDA's), respectively, and subject to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355). The Old formulation of the drug product identified above was being certified until it was exempted from that procedure. It then was released without certification pending a final determination of its effectiveness. In a notice published elsewhere in this issue of the *Federal Register*, the antibiotic regulations are being amended to provide the public standards for the reformulated drug product.)

Therefore, FDA now amends the September 1981 notice: The proposal to withdraw approval of NDA 50-218 does not apply to the NDA as supplemented to provide for the formulation described above.

Among the drugs included in the September 1981 notice were products containing neomycin in combination with a corticosteroid. In a notice published in the *Federal Register* of March 28, 1984 (49 FR 11888), the Director reclassified as effective topical anti-infective combination drug products containing neomycin sulfate and a corticosteroid that were labeled for the treatment of corticosteroid-responsive dermatoses with secondary infection.

The Director has now determined that the addition of polymyxin B sulfate to the combination product of neomycin sulfate and hydrocortisone broadens the

antimicrobial spectrum with little, if any, increase in risk. Accordingly, he reclassifies the reformulated drug product named above as effective for the treatment of corticosteroid-responsive dermatoses with secondary infection. It should be noted, however, that the steroid-antibiotic combination has not been shown to provide greater benefit than the steroid component alone after 7 days of treatment.

The notice is also amended to include the following conditions for approval and marketing of the reformulated product described above.

A. Effectiveness Classification

FDA has reviewed all available evidence and concludes that the drug product is effective for the indication listed in the labeling conditions below. The drug product lacks substantial evidence of effectiveness in its old formulation, and for other indications. This notice does not prevent FDA, in any future OTC drug monograph, from including any of the ingredients listed above, and requiring labeling different from that approval for prescription use.

B. Conditions for Approval and Marketing

FDA is prepared to approve abbreviated new drug applications (antibiotic Form 6 applications) for the formulation now evaluated as effective under conditions described herein.

1. *Form of drug.* This preparation is in cream form suitable for topical administration.

2. *Labeling conditions.* a. The label bears the statement, "Caution: Federal law prohibits dispensing without prescription."

b. The drug is labeled to comply with all requirements of the act and regulations, and the labeling bears adequate information for safe and effective use of the drug. The indication is as follows:

For the treatment of corticosteroid-responsive dermatoses with secondary infection. It has not been demonstrated that this steroid-antibiotic combination provides greater benefit than the steroid component alone after 7 days of treatment. (See "WARNINGS" section.)

c. The "WARNINGS" section contains the following statement:

Because of the concern of nephrotoxicity and ototoxicity associated with neomycin, this combination product should not be used over a wide area or for extended periods of time.

3. *Marketing status of the reformulated product.* The approval and marketing of such drugs are governed by the regulations applicable to antibiotic-

containing drugs. In a notice published elsewhere in this issue of the **Federal Register**, the antibiotic regulations are being amended to provide the public standards for this product. Approval of an abbreviated new drug application (21 CFR 314.2) as an antibiotic Form 6 application (21 CFR 433.1) must be obtained before marketing such product. An abbreviated application will be acceptable only for the formulation specifically named in this notice. Any new combination requires a new drug application, as an antibiotic Form 5 application, and appropriate studies.

The requirements for bioavailability testing are waived for topically applied preparations (21 CFR 320.22). Marketing the drug product before approval of a new drug application will subject that product, and those persons who caused the product to be marketed, to regulatory action.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 507, 52 Stat. 1050-1053 as amended, 59 Stat. 463 as amended (21 U.S.C. 352, 355, 357)) and under authority delegated to the Director of the Center for Drugs and Biologics (21 CFR 5.70 and 5.82).

Dated: April 9, 1985.

Paul Parkman,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 85-9173 Filed 4-16-85; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 85N-0128; DESI 8943]

Oral Acetazolamide; Drugs for Human Use; Request for Revised Labeling

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces that oral acetazolamide is safe and effective for use in preventing or ameliorating acute mountain sickness, and requests that manufacturers of the drug include a recommendation for this use in their labeling. The agency also provides a guideline for adding such a recommendation to labeling.

DATE: This notice is effective on April 17, 1985.

ADDRESSES: Communications in response to this notice should be identified with reference number DESI 8943 and sent to the appropriate office named below:

Supplements to full new drug applications (identify with NDA number): Division of Cardio-Renal Drug Products (HFN-110), Center for Drugs and Biologics, Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857.

Original abbreviated new drug applications and supplements thereto (identify as such): Division of Generic Drug Monographs (HFN-230), Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Published studies supporting action: Dockets Management Branch (HFA-305), Rm. 4-62, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Requests for an opinion of the applicability of this notice to a specific product: Division of Drug Labeling Compliance (HFN-310), Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Douglas I. Ellsworth, Center for Drugs and Biologics (HFN-366), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: In a notice (previously Docket No. FDC-D-306; now Docket No. 85N-0128) published in the **Federal Register** of July 25, 1972 (37 FR 14828), FDA announced its final effectiveness evaluations of the labeling claims made for Diamox Tablets, a conventional release tablet containing 125 milligrams (mg) or 250 mg of acetazolamide (NDA 8-943; held by Lederle Laboratories, Division of American Cyanamide, Pearl River, NY 10965). This notice announced that acetazolamide conventional release tablets are effective for adjunctive treatment of edema due to congestive heart failure; drug-induced edema, centrencephalic epilepsies (petit mal, unlocalized seizures); chronic simple (open angle) glaucoma, secondary glaucoma, and preoperatively in acute angle closure glaucoma where delay of surgery is desired in order to lower intraocular pressure.

Later, in a notice published in the **Federal Register** of March 1, 1973 (38 FR 5490), FDA announced its final effectiveness evaluations of the labeling claims made for Diamox Sequels, a controlled-release formulation containing 500 mg of acetazolamide (NDA 12-945; held by Lederle Laboratories). This notice announced that the controlled-release formulation of acetazolamide is effective for adjunctive treatment of chronic simple (open angle) glaucoma, secondary glaucoma, and preoperatively in acute angle closure glaucoma where delay of surgery is desired in order to lower intraocular pressure.

The above notices, as modified by a notice published in the **Federal Register** of September 22, 1975 (40 FR 43531), set forth conditions for approval and marketing of such drug products. Under these conditions, FDA approved Diamox Tablets and Sequels as effective. In addition, FDA has approved the following abbreviated new drug applications (ANDA's) for acetazolamide 250 mg tablets.

ANDA 84-498; Bolar Pharmaceutical Co., Inc., 130 Lincoln St., Copiague, NY 11726;

ANDA 84-840; The Lannett Co., Inc., 9000 State Rd., Philadelphia, PA 19136;

ANDA 87-654; Vanguard Laboratories, Division of M.W.M. Corp., 103 Samson St., Glasgow, KY 42141; and

ANDA 87-686; Ascot Hospital Pharmaceuticals, Inc., 3055 N. Ridgeway, Skokie, IL 60076.

Recently, under FDA's orphan products development program, which includes evaluations of published data concerning unlabeled uses of marketed drugs where there is evidence of potential benefit in serious conditions or evidence of therapeutic advantage over existing therapy, the agency evaluated published data concerning the use of oral acetazolamide for acute mountain sickness. The agency concluded that the drug is safe and effective for use in the prevention or amelioration of symptoms associated with acute mountain sickness in climbers attempting rapid ascent, and in those who are very susceptible to acute mountain sickness despite gradual ascent (see "Acetazolamide for Acute Mountain Sickness," *FDA Drug Bulletin*, 13(3):27, Nov. 1983). Copies of the published data supporting this conclusion have been placed on file under Docket No. 85N-0128. They may be seen between 9 a.m. and 4 p.m., Monday through Friday, at the Dockets Management Branch (address given above).

Because the agency has concluded that oral acetazolamide is safe and effective for acute mountain sickness, the Director of the Center for Drugs and Biologics requests that the above listed manufacturers add this recommendation for use to their products' labeling. In order to market an oral acetazolamide product that is the subject of an approved application, with a recommendation for use in preventing or ameliorating acute mountain sickness, the holder of the application must supplement the application with revised labeling in accord with this notice and obtain approval of the supplement. The Director also requests that any person seeking approval of an ANDA for an

oral acetazolamide product add to the proposed labeling a recommendation for use in preventing or ameliorating acute mountain sickness, in addition to those labeling recommendations allowed by the July 1972 or March 1973 notices. Guideline labeling is provided below.

Guideline for Adding to Labeling a Recommendation for Use of Oral Acetazolamide in Preventing or Ameliorating Acute Mountain Sickness

The following sections of the labeling should be revised to include the following information (editorially adapted to a specific product's labeling as appropriate):

Indications: Acetazolamide is indicated for the prevention or amelioration of symptoms associated with acute mountain sickness in climbers attempting rapid ascent and in those who are very susceptible to acute mountain sickness despite gradual ascent.

Clinical Pharmacology: Placebo-controlled clinical trials have shown that prophylactic administration of acetazolamide at a dose of 250 mg every 8-12 hours (or a 500 mg controlled release capsule once daily) before and during rapid ascent to altitude results in fewer and/or less severe symptoms (such as headache, nausea, shortness of breath, dizziness, drowsiness, and fatigue) of acute mountain sickness (AMS). Pulmonary function (e.g., minute ventilation, expired vital capacity, and peak flow) is greater in the acetazolamide treated group, both in subjects with AMS and asymptomatic subjects. The acetazolamide-treated climbers also had less difficulty in sleeping.

Precautions: Gradual ascent is desirable to try to avoid AMS. If rapid ascent is undertaken and acetazolamide is used, it should be noted that such use does not obviate the need for prompt descent if severe forms of high altitude sickness occur, i.e., high altitude pulmonary edema (HAPE) or high altitude cerebral edema.

Dosage and Administration: Acetazolamide 250 mg every 8 to 12 hours (or 500 mg controlled-release capsules every 24 hours) has been shown to be effective in expeditioners and tourist-trekkers. Medication should be initiated 24 to 48 hours prior to and continued during ascent, with continuation at altitude as necessary to control symptoms.

For active duty military personnel, the recommended dose is 100 mg daily for 48 hours prior to ascent to high altitude and for 48 hours after arrival (Dept. of Army, 1975, TB Med. 288:10).

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-1053, as amended (21 U.S.C. 352, 355)) and under authority delegated to the Director of the Center for Drugs and Biologics (21 CFR 5.70).

Dated: April 9, 1985.

Harry M. Meyer, Jr.,
Director, Center for Drugs and Biologics.
[FR Doc. 85-9176 Filed 4-16-85; 8:45 am]

BILLING CODE 4160-01-M

Health Care Financing Administration

Statement of Organization, Functions, and Delegations of Authority

Part F. of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Health Care Financing Administration (HCFA) FR, Vol. 48, No. 198, pp. 46439-46440, dated Wednesday, October 12, 1983, and FR, Vol. 49, No. 133, pg. 28117, dated July 10, 1984) is amended to reflect the reorganization of the Office of Program Operations Procedures (OPOP), Bureau of Program Operation (BPO), Office of the Associate Administrator for Operations (OAAO).

The OPOP is being reorganized to make the Office more responsive to program changes by grouping similar program responsibilities. This new structure will eliminate functional overlap and will more evenly distribute workloads.

The specific amendments to the Federal Register are as follows:

Section FP.20.A.3. Office of Program Operations Procedures (FPA4) is amended by deleting the functional statements and organizational titles for the office and the four subordinate divisions and replacing them with new functional statements and organizational titles. The new Section FP.20.A.3. reads as follows:

3. Office of Program Operations Procedures (FPA8)

Develops and promulgates specifications, requirements, methods, systems, standards, and procedures to implement and maintain operational systems for the Medicare and Medicaid programs including detailed definitions of the relative responsibilities of providers, State agencies, contractors HCFA, and the beneficiaries of HCFA's programs. Manages the Medicare contractor workload, establishes priorities, and monitors implementation of major systems changes. Reviews and evaluates systems, systems plans and proposals, and Automated Data Processing acquisition and

modifications involving carriers, intermediaries, and State agencies, and approves Federal Financial Participation in State Medicaid systems. Plans, directs, and coordinates operational policy, systems, and procedures for the establishment and maintenance of Medicare entitlement, premium billing and collection, and Medicaid eligibility activities. Provides oversight of regional offices in managing State Medicaid Management Information Systems (MMIS) and develops systems requirements and specifications for the operation of MMIS. Maintains a National Coding System for use in processing Medicare claims. Provides national oversight of Medicare Management Information Systems.

a. Division of Provider Procedures (FPA81)

Directs the development and issuance of specifications, requirements, procedures, functional standards, and instructional material to implement and maintain operational systems for processing Medicare Part A and outpatient claims and defining their applications to Medicare contractors, providers, suppliers of services, and HCFA. Develops productivity investments and data initiatives designed to promote efficiency and uniformity of operations. Maintains contractor and provider instructional manuals. Serves as the Bureau resource for implementing legislative changes impacting on Part A program operations. Prepares general systems plans and develops requirements for the detailed design and programming for model systems used by Medicare contractors. Plans, conducts, and evaluates studies aimed at long-range improvements in systems, methods, and procedures as they relate to the administration of the Medicare program. Integrates systems within the framework of HCFA policies, goals, and objectives in an efficient and cost-effective manner. Develops, directs, and coordinates systems plans and studies for the effective integration of all Medicare automated and nonautomated processing systems at the contractor level. Designs and conducts studies, demonstrations, and surveys to improve Medicare operational systems, methods, and procedures. Designs and tests new automated information systems and model systems. Conducts reviews and performs analyses for future development and model systems functions in such areas as data management, data base systems analysis and design, distributed processing, terminal operations, minicomputers, and operational

security. Coordinates systems demonstration projects and participates in the review and evaluation of systems-related application projects. Provides direction to, and liaison with, HCFA components involved in the maintenance of health insurance utilization records. Manages contractor-HCFA data exchange systems.

b. Division of Carrier Procedures (FPA82)

Directs the development and issuance of specifications, requirements, procedures, functional standards and instructional material to implement and maintain operational systems for processing Medicare Part B claims and defining their applications to Medicare carriers, providers, suppliers of services, beneficiaries, and HCFA. Manages contractor workloads and sets priorities for workloads which compete for contractor resources. Develops and monitors the implementation of productivity investments and data initiatives designed to promote efficiency and uniformity of operations. Serves as the Bureau resource for implementing legislative changes impacting on Part B program operations. Maintains and issues Medicare Carrier Manual instructions. Manages the annual reasonable charge update process. Prepares general systems plans and develops requirements for the detailed design and programming for carrier systems. Assists in developing systems plans and studies for the effective integration of all Medicare Part B automated and nonautomated processing systems at the contractor level. Assists in studies, demonstrations, and surveys to improve Medicare Part B operational systems, methods, and procedures. Designs and tests new Part B automated information systems. Conducts reviews and performs analyses for the future development of new systems functions in such areas as data management, data base systems analysis and design, distributed processing, terminal operations, minicomputers, and operational security. Coordinates systems demonstration projects and participates in the review and evaluation of systems-related application projects. Assists in the development of systems requirements for Medicare and coordinates systems requirements for related programs. Plans, conducts, and evaluates studies aimed at long-range improvements in systems, methods, and procedures as they relate to the administration of the Medicare program. Integrates systems within the

framework of HCFA policies, goals, and objectives in an efficient and cost-effective manner. Provides direction to, and liaison with, HCFA components involved in the maintenance of health insurance utilization records. Provides for contractor-HCFA data exchange systems.

c. Division of Medicaid Procedures (FP A83)

Develops requirements, standards, procedures, guidelines, and methodologies pertaining to the review, evaluation, and assessment of the operations, development, and funding of State agency automated systems to determine their compliance with published Federal requirements. Designs and employs test criteria to determine the accuracy and effectiveness of Medicaid claims processing systems. Provides technical guidance to other HCFA components involved in Medicaid Management Information Systems (MMIS) oversight functions such as the annual systems performance reviews. Reviews State agency MMIS for approval of increased Federal Financial Participation (FFP). Provides technical assistance to the Office of Program Administration, Bureau of Program Operations, and regional offices with respect to Electronic Data Processing (EDP) procurements and reviews proposed hardware and software modifications and/or equipment upgrades for approval of increased FFP. Establishes technical specifications for EDP procurement procedures and, where appropriate, conducts onsite reviews to determine the necessity and compliance of such procurement requests with the Department of Health and Human Services and HCFA requirements. Develops and maintains a central State data profile to support States and regions in improving operations and serves as a clearinghouse for technical innovations and cost-effective methodologies pertaining to the state of the art in EDP development. Develops, directs, and coordinates systems plans and studies for the effective integration of all Medicaid automated processing systems at the State agency level. Designs and conducts studies, demonstration projects, and surveys to improve Medicaid operational systems, methods, and procedures. Plans, develops, and monitors systems requirements for Medicaid and coordinates systems requirements for related Federal programs such as Child Health Assurance, Child Support Enforcement, Food Stamps, and Aid to Families with Dependent Children. Directs the

development and issuance of regulations, specifications, requirements, procedures, functional standards, and instructional material to implement and maintain operational systems for processing Medicaid claims and defines their application to States and beneficiaries of HCFA programs. Prepares general systems plans and develops requirements for the detailed design and programming for model systems used by States in the administration of the Medicaid program. Plans, conducts, and evaluates studies aimed at long-range improvements in systems, methods, and procedures as they relate to the administration of the Medicaid program. Integrates systems within the framework of HCFA policies, goals, and objectives in an efficient and cost-effective manner. Develops and performs national oversight for MMIS related activity including monitoring regional office responsibilities including automated data processing approvals and MMIS FFP issues in this area. Develops and approves cost allocation plans involving multi-agency programs. Develops data initiatives which will promote efficiency and uniformity in Medicaid operations and directs the implementation of national Title XIX data initiatives such as common coding, uniform bills, and electronic media claims. Develops standards for cost and benefit analysis and monitoring of MMIS design, development, installation, and operations. Serves as HCFA focal point for contact with States and the private sector on MMIS issues. Develops and implements a program for the exchange of information to improve the operation of MMIS systems, methods, and procedures including conferences and other media.

d. Division of Entitlement Requirements (FP A84)

Plans, directs, and coordinates the development of operational policy, systems, and procedures for establishing and maintaining Medicare entitlement records, billing and collecting Medicare premiums, administering State buy-in agreements, and coordinating entitlement for individuals covered under the Medicare program. Assesses the impact of operating systems on beneficiaries of HCFA programs and develops proposals to better meet their needs. Manages use by contractors of telephone, written, and personal communications to provide quality services to Medicare beneficiaries. Reviews the adequacy of services furnished by the Social Security Administration (SSA) in establishing

entitlement for Medicare beneficiaries and collecting premiums. Prepares and releases instructional material to SSA district offices on the entitlement, premium, and buy-in processes. Issues instructions to SSA and SSA Field offices on resolving entitlement, premium, and buy-in problems and assists in resolving individual problems of beneficiaries when normal processes fail. Manages premium collections for billable individuals, third-party groups, and the State buy-in program.

Dated: March 8, 1985.

James L. Scott,

Acting Administrator, Health Care Financing Administration.

[FR Doc. 85-9181 Filed 4-16-85; 8:45 am]

BILLING CODE 4120-03-M

Public Health Service

Advisory Council; Establishment

Pursuant to the Federal Advisory Committee Act, Pub. L. 92-463 (5 U.S.C. App. I), the National Center for Health Services Research and Health Care Technology Assessment announces the establishment by the Secretary, HHS, of the National Advisory Council on Health Care Technology Assessment on March 20, 1985, pursuant to Pub. L. 98-551, the Health Promotion and Disease Prevention Amendments of 1984.

Designation: National Advisory Council on Health Care Technology Assessment.

Purpose: The Council will provide advice to the Secretary and to the Director of the National Center for Health Services Research and Health Care Technology Assessment concerning health care technology issues and to assist in developing criteria and methods to determine whether specific health care technologies should be reimbursable under federally-financed health care programs. The Council will also review and make recommendations on research grant and contract applications over \$50,000 in the area of health care technology.

Authority for this is in statute so the Council will continue in existence until the statute is modified.

Dated: April 4, 1985.

John E. Marshall,

Director, National Center for Health Services Research and Health Care Technology Assessment.

[FR Doc. 85-9193 Filed 4-16-85; 8:45 am]

BILLING CODE 4160-17-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[Docket No. 4-20703-ILM]

Proposed Withdrawal and Opportunity for Public Meeting, Petroglyph Canyon and Weatherman's Draw Prehistoric Rock Art Sites, Carbon, County, MT

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management proposes to withdraw 840 acres of public land for administrative purposes associated with Petroglyph Canyon and Weatherman's Draw Prehistoric Rock Art Sites, Carbon County, Montana. This notice closes the land for up to 2 years from surface entry and mining. The land will remain open to mineral leasing.

DATE: Comments and requests for public meetings should be received by July 16, 1985.

ADDRESS: Comments and meeting requests should be sent to: Montana State Director, Bureau of Land Management, P.O. Box 36800, Billings, Montana 59107.

FOR FURTHER INFORMATION CONTACT: James Binando, Montana State Office, 406-657-6090.

SUPPLEMENTARY INFORMATION:

On March 29, 1985, a petition was approved allowing the Bureau of Land Management to file an application to withdraw the following described land from settlement, sale, location, or entry under the general public land laws, including the mining laws, subject to valid existing rights.

Principal Meridian, Montana

T. 9 S., R. 26 E.,
Sec. 35, lots 2, 3, 6, 7, SW $\frac{1}{4}$ NE $\frac{1}{4}$ and SE $\frac{1}{4}$ NW $\frac{1}{4}$.
T. 8 S., R. 24 E.,
Sec. 20, SE $\frac{1}{4}$ SW $\frac{1}{4}$ and S $\frac{1}{2}$ SE $\frac{1}{4}$;
Sec. 29, E $\frac{1}{2}$ and E $\frac{1}{2}$ W $\frac{1}{2}$.

The area described contains 840 acres in carbon County.

The purpose of the proposed withdrawal is to protect prehistoric rock art sites.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal may present their views in writing to the Montana State Director of the Bureau of Land Management.

Notice is hereby given that an opportunity for a public meeting is afforded in connection with the proposed withdrawal. All interested

persons who desire a public meeting for the purpose of being heard on the proposed withdrawal must submit a written request to the Montana State Director within 90 days from the date of publication of this notice. Upon determination by the authorized officer that a public meeting will be held, a notice of the time and place will be published in the *Federal Register* at least 30 days before the scheduled date of the meeting.

The application will be processed in accordance with the regulations set forth in 43 CFR Part 2300.

For a period of 2 years from the date of publication of this notice in the *Federal Register*, the lands will be segregated as specified above unless the application is denied or canceled or the withdrawal is approved prior to that date. No temporary uses will be permitted during this segregative period. John A. Kwiatkowski,

Deputy State Director, Division of Lands and Renewable Resources.

April 8, 1985.

[FR Doc. 85-9210 Filed 4-16-85; 8:45 am]

BILLING CODE 4310-DN-M

Wyoming; Worland District Multiple Use Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior, Worland District Office, Worland, Wyoming.

ACTION: Meeting of the Worland District Multiple Use Advisory Council.

SUMMARY: Notice is hereby given in accordance with Pub. L. 91-463, 94-578, and 95-514, and 43 CFR Part 1780, that a meeting of the Worland District Multiple Use Advisory Council will be held on May 16, 1985, at 10:00 a.m., at the Worland Elk's Lodge.

Agenda items for the meeting are the following:

1. Washakie Resource Management Plan
2. Grass Creek/Cody Wilderness EIS
3. BLM/USFS Interchange Program
4. Resource Area Adjustments
5. Grazing Issues
6. Realty Actions
7. Access
8. Habitat Management Plans
9. Allotment Categorization
10. Worland District Office Building
11. North Fork Well EIS
12. Wild Horses

The meeting is open to the public. Interested persons may make oral statements to the Council at specified times during the meeting, or file written statements for the consideration of the

Council. Anyone wishing to make an oral statement must notify the District Manager by May 9, 1985. Depending on the number of persons wanting to make oral statements, a per-person time limit may be established.

SUPPLEMENTARY INFORMATION:

Summary minutes of this meeting will be maintained in the Worland District Office and will be available for public inspection during regular business hours.

DATE: May 16, 1985, 10:00 a.m.

ADDRESS: Elk's Lodge, 604 Coburn Avenue, Worland, Wyoming.

FOR FURTHER INFORMATION CONTACT:

Chester E. Conard, District Manager, Bureau of Land Management, P.O. Box 119, Worland, Wyoming 82401. Telephone: (307) 347-9871.

Edward L. Fisk,

Associate District Manager.

[FR Doc. 85-9286 Filed 4-16-85; 8:45 am]

BILLING CODE 4310-22-M

Minerals Management Service

Alaska Offshore; Availability of the Final Environmental Impact Statement for Proposed Oil and Gas Lease Sale 89 in the St. George Basin

Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, the Minerals Management Service has prepared a final environmental impact statement (EIS) for proposed oil and gas Lease Sale 89 in St. George Basin.

Single copies of the final EIS can be obtained from the Office of the Regional Director, Minerals Management Service, Alaska Region, P.O. Box 101159, Anchorage, Alaska 99510.

Copies of the final EIS will also be available for inspection in the following public libraries: Alaska Federation of Natives, Suite 304, 1577 O Street, Anchorage, AK 99501; Anchor Point Public Library, Anchor Point, AK 99556; Department of the Interior Resource Library, Box 36, 701 C Street, Anchorage, AK 99513; Cordova Public Library, Box 472, Cordova, AK 99574; Kenai Community Library, Box 157, Kenai, AK 99611; Elim Learning Center, Elim, AK 99739; Haines Public Library, P.O. Box 38, Haines, AK 99827; North Star Borough Library, Fairbanks, AK 99701; University of Alaska, Institute of Social and Economic Research Library, Fairbanks, AK 99801; Homer Public Library, Box 356, Homer, AK 99603; Z.J. Loussac Public Library, 427 F Street, Anchorage, AK 99801; Juneau Memorial Library, 114 W. 4th Street, Juneau, AK 99824; Alaska State Library, Documents

Librarian, Pouch G, Juneau, AK 99811; Ketchikan Public Library, 629 Dock Street, Ketchikan, AK 99901; Department of Defense, Army Corps of Engineers Library, P.O. Box 7002, Anchorage, AK 99501; Kodiak Public Library, P.O. Box 985, Kodiak, AK 99615; Metlakatla Extension Center, Metlakatla, AK 99926; Department of the Interior, Bureau of Mines Library, AF-F.O. Center, P.O. Box 550, Juneau, AK 99802; Petersburg Extension Center, Box 289, Petersburg, AK 99833; Seldovia Public Library, Drawer D, Seldovia, AK 99663; Seward Community Library, Box 537, Seward, AK 99864; University of Alaska Juneau Library, P.O. Box 1447, Juneau, AK 91447; Sitka Community Library, Box 1090, Sitka, AK 99835; Douglas Public Library, Box 469, Douglas, AK 99824; University of Alaska Anchorage Library, 3211 Providence Drive, Anchorage, AK 99504; University of Alaska Elmer E. Rasmuson Library, Fairbanks, AK 99701; Wrangell Extension Center, Box 651, Wrangell, AK 99929.

Ralph D. Fazio,

Acting Director, Minerals Management Service.

Approved:

Bruce Blanchard,

Director, Environmental Project Review.

[FR Doc. 85-9218 Filed 4-16-85; 8:45 am]

BILLING CODE 4310-MR-M

Corpus Christi Oil and Gas Co.; Development Operations Coordination Document

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of the Receipt of a Proposed Development Operations Coordination Document (DOCD).

SUMMARY: Notice is hereby given that Corpus Christi Oil and Gas Company has submitted a DOCD describing the activities it proposes to conduct on Lease OCS-G 4258, Block 436, Brazos Area, offshore Texas. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from an onshore base located at Port O'Connor, Texas.

DATE: The subject DOCD was deemed submitted on April 4, 1985.

ADDRESS: A copy of the subject DOCD is available for public review at the Office of the Regional Director, Gulf of Mexico OCS Region, Minerals Management Service, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana (Office Hours: 9 a.m. to 3:30 p.m., Monday through Friday).

FOR FURTHER INFORMATION CONTACT:

Mr. Michael J. Tolbert; Minerals Management Service; Gulf of Mexico OCS Region; Rules and Production; Plans, Platform and Pipeline Section; Exploration/Development Plans Unit; Phone (504) 838-0875.

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to inform the public, pursuant to section 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs available to affected states, executives of affected local governments, and other interested parties became effective December 13, 1979 (44 FR 53685). Those practices and procedures are set out in revised § 250.34 of Title 30 of the CFR.

Dated: April 5, 1985.

John L. Rankin,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 85-9208 Filed 4-16-85; 8:45 am]

BILLING CODE 4310-MR-M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731-TA-189 (Final)]

Calcium Hypochlorite From Japan

Determination

On the basis of the record¹ developed in the subject investigation, the Commission determines,² pursuant to section 735(b)(1) of the Tariff Act of 1930 (19 U.S.C. 1673(b)(1)), that an industry in the United States is materially injured by reason of imports from Japan of calcium hypochlorite, provided for in item 418.22 of the Tariff Schedules of the United States, which have been found by the department of Commerce to be sold in the United States at less than fair value (LTFV).

Background

The Commission instituted this investigation effective October 9, 1984, following a preliminary determination by the Department of Commerce that imports of calcium hypochlorite from Japan were being sold at LTFV within the meaning of section 731 of the Act (19

¹ The record is defined in sec. 207.2(i) of the Commission's rules of practice and procedure (19 CFR 207.2(i)).

² Vice Chairman Liebel and Commissioner Lodwick dissenting.

U.S.C. 1673). Notice of the institution of the Commission's investigation and of a public hearing to be held in connection therewith was given by posting copies of the notices in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the *Federal Register* of October 31, 1984 (49 FR 43807). A notice revising the Commission's schedule for the conduct of the investigation was published in the *Federal Register* of November 28, 1984 (49 FR 46817). The hearing was held in Washington, DC, on February 26, 1985, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determination in this investigation to the Secretary of Commerce on April 8, 1985. The views of the Commission are contained in USITC Publication 1672 (April 1985), entitled "Calcium Hypochlorite from Japan: Determination of the Commission in Investigation No. 731-TA-189 (Final) Under the Tariff Act of 1930, Together with the Information Obtained in the Investigation."

Issued: April 8, 1985.

By Order of the Commission.

Kenneth R. Mason,
Secretary.

[FR Doc. 85-9228 Filed 4-16-85; 8:45 am]

BILLING CODE 7020-02-M

[Investigation Nos. 701-TA-243 and 244 (Preliminary) and 731-TA-256 Through 258 (Preliminary)]

Carbon Steel Wire Rod From Poland, Portugal, and Venezuela

AGENCY: United States International Trade Commission.

ACTION: Institution of preliminary countervailing duty and antidumping investigations and scheduling of a conference to be held in connection with the investigations.

SUMMARY: The Commission hereby gives notice of the institution of preliminary countervailing duty investigations Nos. 701-TA-243 and 244 (Preliminary) under section 703(a) of the Tariff Act of 1930 (19 U.S.C. 1671(a)) and of preliminary antidumping investigations Nos. 731-TA-256, 257, and 258 (Preliminary) under section 733(a) of the Tariff Act of 1930 (19 U.S.C. 1673b(a)) to determine whether there is a reasonable indication that an industry in the United States is materially injured, or is threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports from Portugal and Venezuela of

carbon steel wire rod, provided for in item 607.17 of the Tariff Schedules of the United States, which are alleged to be subsidized by the Governments of Portugal and Venezuela, and of carbon steel wire rod from Poland, Portugal, and Venezuela which are alleged to be sold in the United States at less than fair value. As provided in sections 703(a) and 733(a), the Commission must complete preliminary countervailing duty and antidumping investigations in 45 days, or in this case by May 23, 1985.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's rules of practice and procedure, part 207, subparts A and B (19 CFR Part 207), and Part 201, Subparts A through E (19 CFR Part 201, as amended by 49 FR 32569, Aug. 15, 1984).

EFFECTIVE DATE: April 8, 1985.

FOR FURTHER INFORMATION CONTACT:

George L. Deyman (202-523-0481), Office of Investigations, U.S. International Trade Commission, 701 E Street NW., Washington, DC 20436.

SUPPLEMENTARY INFORMATION:

Background.

These investigations are being instituted in response to petitions filed on April 8, 1985, by Atlantic Steel Co., Atlanta, GA; Continental Steel Corp., Kokomo, IN; Georgetown Steel Corp., Georgetown, SC; Nother Star Steel Texas, Inc., Beaumont, TX; and Raritan River Steel Co., Perth Amboy, NJ.

Participation in the investigations.

Persons wishing to participate in these investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11 of the Commission's rules (19 CFR 201.11), not later than seven (7) days after publication of this notice in the *Federal Register*. Any entry of appearance filed after this date will be referred to the Chairwoman, who will determine whether to accept the late entry for good cause shown by the person desiring to file the entry.

Service list.

Pursuant to § 201.11(d) of the Commission's rules (19 CFR 201.11(d)), the Secretary will prepare a service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance. In accordance with § 201.16(c) of the rules (19 CFR 201.16(c)), as amended by 49 FR 32569, Aug. 15, 1984, each document filed by a party to the investigations must be served on all other parties to

the investigations (as identified by the service list), and a certificate of service must accompany the document. The Secretary will not accept a document for filing without a certificate of service.

Conference.

The Commission's Director of Operations has scheduled a conference in connection with these investigations for 9:30 a.m. on April 30, 1985 at the U.S. International Trade Commission Building, 701 E Street NW., Washington, DC. Parties wishing to participate in the conference should contact George L. Deyman (202-523-0481) not later than April 26, 1985 to arrange for their appearance. Parties in support of the imposition of countervailing and/or antidumping duties in these investigations and parties in opposition to the imposition of such duties will each be collectively allocated one hour within which to make an oral presentation at the conference.

Written submissions.

Any person may submit to the Commission on or before May 3, 1985 a written statement of information pertinent to the subject of the investigations, as provided in § 207.15 of the Commission's rules (19 CFR 207.15). A signed original and fourteen (14) copies of each submission must be filed with the Secretary to the Commission in accordance with § 201.8 of the rules (19 CFR 201.8, as amended by 49 FR 32569, Aug. 15, 1984). All written submissions except for confidential business data will be available for public inspection during regular business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary to the Commission.

Any business information for which confidential treatment is desired must be submitted separately. The envelope and all pages of such submissions must be clearly labeled "Confidential Business Information." Confidential submissions and requests for confidential treatment must conform with the requirements of section 201.6 of the Commission's rules (19 CFR 201.6, as amended by 49 FR 32569, Aug. 15, 1984).

AUTHORITY: These investigations are being conducted under authority of the Tariff Act of 1930, title VII. This notice is published pursuant to § 207.12 of the Commission's rules (19 CFR 207.12).

Issued: April 11, 1985.

By order of the Commission.

Kenneth R. Mason,
Secretary.

[FR Doc. 85-9232 Filed 4-16-85; 8:45 am]

BILLING CODE 7020-02-M

[Investigation No. 337-TA-195]**Certain Cloisonne Jewelry; Commission Decision Not To Review Initial Determination; Deadline for Filing Written Submission on Remedy, the Public Interest and Bonding****AGENCY:** U.S. International Trade Commission.

ACTION: Notice is hereby given that the Commission has determined not to review the administrative law judge's initial determination that there is a violation of section 337 in the above-captioned investigation. The parties to the investigation and interested Government agencies are requested to file written submissions on the issues of remedy, the public interest, and bonding:

SUMMARY: On March 6, 1985, the administrative law judge issued an initial determination that there is a violation of section 337 in the importation and sale of certain cloisonne jewelry. No petitions for review or comments from government agencies or the public have been received. Having examined the record in this investigation, including the initial determination, the Commission has determined not to review the initial determination. Consequently, the initial determination has become the Commission determination on violation of section 337 in this investigation.

AUTHORITY: The authority for the Commission's disposition of this matter is contained in section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) and in §§ 210.53-56 of the Commission's rules of practice and procedure (as amended by 49 FR 46123 (November 23, 1984) to be codified at 19 CFR 210.53-56).

FOR FURTHER INFORMATION CONTACT: Judith M. Czako, Esq., Office of the General Counsel, U.S. International Trade Commission, telephone 202-523-0359.

SUPPLEMENTARY INFORMATION: *Written submissions:* Inasmuch as the Commission has found that a violation of section 337 has occurred, it may issue (1) an order which could result in the exclusion of the subject articles from entry into the United States and/or (2) cease and desist orders which could result in one or more respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions which address the form of

relief, if any, which should be ordered.

If the Commission contemplates some form of relief, it must consider the effects of that relief upon the public interest. The factors which the Commission will consider include the effect that an exclusion order and/or a cease and desist order would have upon (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) the U.S. production of articles which are like or directly competitive with those which are the subject of the investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions concerning the effect, if any, that granting relief would have on the public interest.

If the Commission orders some form of relief, the President has 60 days to approve or disapprove the Commission's action. During this period, the subject articles would be entitled to enter the United States under a bond in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving written submissions concerning the amount of the bond, if any, which should be imposed.

The parties to the investigation and interested Government agencies are requested to file written submissions on the issues of remedy, the public interest, and bonding. The complainant and the Commission investigative attorney are also requested to submit a proposed exclusion order and/or a proposed cease and desist order for the Commission's consideration. Persons other than the parties and Government agencies may file written submissions addressing the issues of remedy, the public interest, and bonding must be filed not later than the close of business on the day which is fourteen (14) days from the date this notice appears in the **Federal Register**. Written submissions in reply to the submissions on remedy, the public interest, and bonding must be filed not later than the close of business on the day which is twenty-one (21) days from the date this notice appears in the **Federal Register**.

Commission hearing: The Commission does not plan to hold a public hearing in connection with final disposition of this investigation.

Additional information: Persons submitting written submissions must file the original document and 14 true copies thereof with the Office of the Secretary on or before the deadline stated above. Any person desiring to submit a

document (or a portion thereof) to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment by the administrative law judge. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. Documents containing confidential information approved by the Commission for confidential treatment will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Secretary's Office.

Notice of this investigation was published on the **Federal Register** of June 6, 1984 (49 FR 23461).

Copies of the nonconfidential version of the administrative law judge's initial determination and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 701 E Street NW., Washington, D.C. 20436, telephone 202-523-0161.

By order of the Commission.

Issued: April 9, 1985.

Kenneth R. Mason,
Secretary.

[FR Doc. 85-9230 Filed 4-16-85; 8:45 am]

BILLING CODE 7020-02-M

[Investigation No. 337-TA-197]**Certain Compound Action Metal Cutting Snips and Components Thereof; Receipt of Initial Determination Terminating Respondent on the Basis of Consent Order Agreement****AGENCY:** U.S. International Trade Commission.

ACTION: Notice is hereby given that the Commission has received an initial determination from the presiding officer in the above-captioned investigation terminating the following respondent on the basis of a consent order agreement: U.S. General Supply Corporation.

SUPPLEMENTARY INFORMATION: This investigation is being conducted pursuant to section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). Under the Commission's rules, the presiding officer's initial determination will become the determination of the

Commission thirty (30) days after the date of its service upon the parties, unless the Commission orders review of the initial determination. The initial determination in this matter was served upon the parties on April 10, 1985.

Copies of the initial determination, the consent order agreement, and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 701 E Street NW., Washington, D.C. 20436, telephone 202-523-0161.

Written comments: Interested persons may file written comments with the Commission concerning termination of the aforementioned respondent. The original and 14 copies of all such comments must be filed with the Secretary to the Commission, 701 E Street NW., Washington, D.C. 20436, no later than 10 days after publication of this notice in the *Federal Register*. Any person desiring to submit a document (or portion thereof) to the Commission in confidence must request confidential treatment. Such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why confidential treatment should be granted. The Commission will either accept the submission in confidence or return it.

FOR FURTHER INFORMATION CONTACT: Ruby J. Dionne, Office of the Secretary, U.S. International Trade Commission, telephone 202-523-0176.

By order of the Commission.

Issued: April 8, 1985.

Kenneth R. Mason,
Secretary.

[FR Doc. 85-9229 Filed 4-16-85; 8:45 am]

BILLING CODE 7020-02-M

[Investigations Nos. 701-TA-239 (Preliminary) and 731-TA-248 (Preliminary)]

Certain Ethyl Alcohol From Brazil

Determination

On the basis of the record¹ developed in the subject investigations, the Commission determines, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673(a)), that there is a reasonable indication that an industry in the United States is threatened with material injury by reason of imports from Brazil of

certain ethyl alcohol,² provided for in item 427.88 of the Tariff schedules of the United States, which are alleged to be subsidized by the Government of Brazil (Investigation No. 701-TA-239 (Preliminary)) and which are alleged to be sold in the United States at less than fair value (LTFV) (Investigation No. 731-TA-248 (Preliminary)).

Background

On February 25, 1985, petitions were filed with the Commission and the Department of Commerce by Counsel on behalf of the Ad Hoc Committee of Domestic Fuel Ethanol Producers, alleging that an industry in the United States is materially injured or threatened with material injury by reason of subsidized and LTFV imports of certain ethyl alcohol from Brazil. Accordingly, effective February 25, 1985, the Commission instituted preliminary countervailing duty investigation No. 701-TA-239 (Preliminary) and preliminary antidumping investigation No. 731-TA-248 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the *Federal Register* of March 6, 1985 (50 FR 9136). The conference was held in Washington, DC, on March 19, 1985, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determination in this investigation to the Secretary of Commerce on April 11, 1985. The views of the Commission are contained in USITC Publication 1678 (April 1985), entitled "Certain Ethyl Alcohol from Brazil: Determination of the Commission in Investigation No. 701-TA-239 (Preliminary) and Investigation No. 731-TA-248 (Preliminary) Under the Tariff Act of 1930, Together With the Information Obtained in the Investigations."

Issued: April 12, 1985.

By order of the Commission.

Kenneth R. Mason,
Secretary.

[FR Doc. 85-9233 Filed 4-16-85; 8:45 am]

BILLING CODE 7020-02

² The ethyl alcohol (ethanol) included in these investigations is fuel ethanol (fuel-grade ethanol) imported under item 427.88 of the Tariff Schedules of the United States (TSUS) and subject to additional duties under TSUS item 901.50.

[Investigation No. 337-TA-185]

Certain Rotary Wheel Printing Systems; Commission Decision To Review Initial Determination and Schedule for Filing of Written Submissions on Violation and on Relief, the Public Interest, and Bonding; Notice of Commission Hearing; Notice of Extension of Administrative Deadline for Completion of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice is hereby given that the Commission has determined to review the administrative law judge's initial determination that there is a violation of section 337 of the Tariff Act of 1930 in the above-captioned investigation.

AUTHORITY: The authority for the Commission's disposition of this matter is contained in section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) and in sections 210.53-56 of the Commission's rules of practice and procedure (49 FR 46123 (Nov. 23, 1984); to be codified at 19 CFR 210.53-56).

FOR FURTHER INFORMATION CONTACT: Charles H. Nalls, Esq., Office of the General Counsel, U.S. International Trade Commission, telephone 202-523-1626.

SUPPLEMENTARY INFORMATION: On February 15, 1985, the administrative law judge issued an initial determination that there is a violation of section 337 in the importation and sale of certain rotary wheel printing systems. Respondents petitioned for review of various parts of the initial determination pursuant to § 210.54(a) of the Commission's rules.

After examining the petitions for review and the responses thereto, the Commission has concluded that there are issues that warrant review. Specifically, the commission will review the following questions:

1. Whether U.S. Letters Patent 4,118,129 (the '129 patent) is invalid by virtue of anticipation within the meaning of 35 U.S.C. 102(g).
2. Whether the '129 patent is invalid as obvious within the meaning of 35 U.S.C. 103.
3. Whether the '129 patent is invalid for failure to disclose "best mode" as required by 35 U.S.C. 112.
4. Whether the '129 patent is unenforceable by reason of inequitable conduct before the United States Patent and Trademark Office in connection with the patent applicant's alleged failure to disclose relevant prior art consisting of the Hy Type I printer and manual and certain optical encoders manufactured by Litton and Disc.

¹ The record is defined in sec. 207.2(i) of the Commission's rules of practice and procedure (19 CFR 207.2(i)).

5. Whether the devices manufactured and imported by respondents infringe claim 8 of the '129 patent. The Commission is especially interested in the effect, if any, of prosecution history estoppel on the question of infringement under the doctrine of equivalents.

6. Whether the importation or sale of respondents' devices has the effect or tendency to destroy or substantially injure an "industry, . . . in the United States."

If the Commission finds that a violation of section 337 has occurred, it may issue (1) an order which could result in the exclusion of the subject articles from entry into the United States and/or (2) cease and desist orders which could result in one or more respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions which address the form of relief, if any, which should be ordered.

If the Commission concludes that a violation of section 337 has occurred and contemplates some form of relief, it must consider the effect of that relief upon the public interest. The factors which the Commission will consider include the effect that an exclusion order and/or cease and desist order would have upon (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) the U.S. production of articles which are like or indirectly competitive with those which are the subject of the investigation, and (4) U.S. consumers.

If the Commission finds that a violation of section 337 has occurred and orders some form of relief, the President has 60 days to approve or disapprove the Commission's action. During this period, the subject articles would be entitled to enter the United States under a bond in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving written submissions concerning the amount of the bond, which should be imposed.

Extension of Administrative Deadline

Because of the complex nature of the issues in this case, the Commission, under section 337(b)(1) and § 210.59 of the Commission's rules of practice and procedure (49 FR 46139, Nov. 23, 1984), designated this investigation "more complicated" and extended the original deadline for completion of the investigation by 61 days, i.e., until May 7, 1985, 49 FR 35873 (September 12, 1984). In light of the relatively short period of time remaining before the

expiration of that deadline, the extent of the review undertaken, and the need for a Commission hearing, the Commission has extended the administrative deadline for completion of the investigation to August 12, 1985.

Commission Hearing

The Commission will hold a public hearing on May 28, 1985, in the Commission's Hearing Room, 701 E Street, NW, Washington, D.C. 20436, beginning at 10:00 a.m. The hearing will be divided into two parts. First the Commission will hear oral arguments on the issues under review. Second, the Commission will hear presentations concerning appropriate relief, the effect that such relief would have upon the public interest, and the proper amount of the bond in the event that the Commission determines that there is a violation of section 337 and that relief should be granted. These matters will be heard on the same day in order to facilitate the completion of this investigation within time limits established under law and to minimize the burden upon the parties.

Oral Arguments

Parties to the investigation and interested Government agencies may present oral arguments concerning the issues under review. That portion of a party's or an agency's total time allocated to oral argument may be used in any way the party or agency making argument sees fit, i.e., a portion of the time may be reserved for rebuttal or devoted to summation. The oral arguments will be held in the following order: complainant, respondents, Government agencies, and the commission investigative attorney. Persons making oral argument are reminded that such argument must be based upon the evidentiary record certified to the Commission by the administrative law judge.

Oral Presentations on Relief, the Public Interest, and Bonding

Following the oral arguments on the issues under review, parties to the investigation, Government agencies, public-interest groups, and interested members of the public may make oral presentations on the issues of relief, the public interest, and bonding. This portion of the hearing is quasi-legislative in nature; presentations need not be confined to the evidentiary record certified to the Commission by the administrative law judge, and may include testimony of witnesses. Oral presentations on relief, the public interest, and bonding will be heard in this order: complaint, respondents,

Government agencies, the Commission investigative attorney, public interest groups, and interested members of the public.

Time Limit for Oral Argument and Oral Presentation

Complainant, respondents (taken together), the Commission investigative attorney, and Government agencies will be limited to a total of 30 minutes (exclusive of time consumed by questions from the Commission or its advisory staff) for making both oral argument on violation and oral presentations on relief, the public interest, and bonding. Persons making presentations solely on relief, the public interest, and bonding will be limited to 10 minutes (exclusive of time consumed by questions from the Commission or its advisory staff). The Commission may in its discretion expand the aforementioned time limits upon receipt of a timely request to do so.

Written Submissions

In order to give greater focus to the hearing, the parties to the investigation and interested Government agencies are encouraged to file written submissions on the legal issues under review and on the issues of relief, the public interest, and bonding. Complainant and the Commission investigative attorney are also requested to submit a proposed exclusion order and/or a proposed cease and desist order for the Commission's consideration. Persons other than the parties and Government agencies may file written submissions addressing the issues of relief, the public interest, and bonding.

Written submissions on the issues under review must be filed not later than the close of business on April 24, 1985, and submissions on relief, the public interest, and bonding must be filed not later than the close of business on May 3, 1985. Reply submissions on the issues under review and on relief, the public interest, and bonding must be filed not later than May 10, 1985.

Additional Information

Persons submitting written submissions must file the original document and 14 true copies thereof with the Office of the Secretary on or before the deadlines stated above. Any person desiring to submit a document (or portion thereof) to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment by the administrative law judge. All such requests should be directed to the Secretary to the Commission and must

include a full statement of the reasons why the Commission should grant such treatment. Documents containing confidential information approved by the Commission for confidential treatment will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

Notice of this investigation was published in the *Federal Register* of March 7, 1984 (49 FR 85027).

Copies of the nonconfidential version of the administrative law judge's initial determination and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 701 E Street NW., Washington, D.C. 20436, telephone 202-523-0161.

Issued: April 10, 1985.

By order of the Commission.

Kenneth R. Mason,

Secretary.

[FR Doc. 85-9231 Filed 4-16-85; 8:45 am]

BILLING CODE 7020-02-M

**[Investigation No. 701-TA-238
(Preliminary)]**

Low-Fuming Brazing Copper Wire and Rod From New Zealand

AGENCY: United States International Trade Commission.

ACTION: Termination of investigation.

SUMMARY: On March 27, 1985, the Commission was notified by the United States Trade Representative that, effective April 1, 1985, the obligations of the Agreement on Interpretation and Application of Articles VI, XVI, and XXIII of the General Agreement on Tariffs and Trade (the Subsidies Code) will not apply between the United States and New Zealand. Accordingly, as of that date, New Zealand is no longer a "country under the Agreement" within the meaning of the Tariff Act of 1930 and is not entitled to an injury determination in countervailing duty investigations. The Commission is, therefore, terminating preliminary countervailing duty investigation No. 701-TA-238 (Preliminary).

EFFECTIVE DATE: April 1, 1985.

FOR FURTHER INFORMATION CONTACT: Cynthia Wilson (202-523-0291), Office of Investigations, U.S. International Trade Commission, 701 E Street NW., Washington, DC 20436.

Authority: This investigation is being terminated under authority of the Tariff Act of 1930, title VII. This notice is published pursuant to § 207.40 of the Commission's rules (19 CFR 207.40).

Issued: April 5, 1985.

By order of the Commission.

Kenneth R. Mason,

Secretary.

[FR Doc. 85-9234 Filed 4-16-85; 8:45 am]

BILLING CODE 7020-02-M

**[Investigation No. 731-TA-244
(Preliminary)]**

Natural Bristle Paint Brushes From the People's Republic of China

Determination

On the basis of the record¹ developed in the subject investigation, the Commission determines, pursuant to section 733(a) of the Tariff Act of 1930 (19 U.S.C. 1673b(a)), that there is a reasonable indication that an industry in the United States is threatened with material injury² by reason of imports from the People's Republic of China of natural bristle paint brushes, except artists' brushes, provided for in item 750.65 of the Tariff Schedules of the United States, which are alleged to be sold in the United States at less than fair value (LTFV).

Background

On February 19, 1985, a petition was filed with the Commission and the Department of Commerce by the United States Paint Brush Manufacturers and Suppliers Ad Hoc Import Action Coalition, Washington, DC, alleging that an industry in the United States is materially injured or threatened with material injury by reason of LTFV imports of natural bristle paint brushes from the People's Republic of China. Accordingly, effective February 19, 1985, the Commission instituted preliminary antidumping investigation No. 731-TA-244 (Preliminary).

Notice of the institution of the Commission's investigation and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the *Federal Register* of March 6, 1985 (50 FR 9138). The conference was held in Washington, DC, on March 15, 1985, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determination in this investigation to the

¹The record is defined in sec. 207.2(i) of the Commission's rules of practice and procedure (19 CFR 207.2(i)).

²Commissioners Eckes and Rohr also determined that there was a reasonable indication that an industry in the United States is materially injured by reason of imports from the People's Republic of China of natural bristle paint brushes, except artists' brushes, which are alleged to be sold in the United States at LTFV.

Secretary of Commerce on April 5, 1985. The views of the Commission are contained in USITC Publication 1674 (April 1985), entitled "Natural Bristle Paint Brushes from the People's Republic of China; Determination of the Commission in Investigation No. 244 (Preliminary) Under the Tariff Act of 1930, Together With the Information Obtained in the Investigation."

Issued: April 8, 1985.

By order of the Commission.

Kenneth R. Mason,

Secretary.

[FR Doc. 85-9227 Filed 4-16-85; 8:45 am]

BILLING CODE 7020-02-M

**INTERSTATE COMMERCE
COMMISSION**

**Forms under review by Office of
Management and Budget**

The following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35) is being submitted to the Office of Management and Budget for review and approval. Copies of the forms and supporting documents may be obtained from the Agency Clearance Officer, Ray Houser (202) 275-6723. Comments regarding this information collection should be addressed to Ray Houser, Interstate Commerce Commission, Room 1325, 12th and Constitution Avenue, NW., Washington, DC 20423 and to Gary Waxman, Office of Management and Budget, Room 3228 NEOB, Washington, DC 20503, (202) 395-7340.

Type of Clearance: New
Bureau/Office: Office of Proceedings
Title of Form: Applications for
Certificates of Registration for certain
Motor Carriers of Property under
Section 10530 of the IC Act
OMB Form No.: N/A
Agency Form No.: OP-2
Frequency: Annual
Respondents: Foreign motor carriers of
Property
No. of Respondents: 5,000
Total Burden Hrs.: 5,000

James H. Bayne,

Secretary.

[FR Doc. 85-9235 Filed 4-16-85; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-19 (Sub.104X)]

**The Baltimore & Ohio Railroad Co.;
Abandonment in Fayette County, PA;
Exemption**

Applicant has filed a notice of

exemption under 49 CFR Part 1152 Subpart F—*Exempt Abandonments* to abandon its line of railroad between valuation station 21+40 and valuation station 66+23, at or near Uniontown, PA.

Applicant has certified (1) that no local traffic has moved over the line for at least 2 years and that overhead traffic is not moved over the line or may be rerouted, and (2) that no formal complaint filed by a user of rail service on the line (or by a State or local governmental entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Commission or has been decided in favor of the complainant within the 2-year period. The appropriate State agency has been notified in writing at least 10 days prior to filing of this notice.

As a condition to use of this exemption, any employee affected by the abandonment shall be protected pursuant to *Oregon Short Line R. Co.—Abandonment—Goshen*, 360 I.C.C. 91 (1979).

The exemption will be effective May 17, 1985 (unless stayed pending reconsideration). Petitions to stay must be filed by April 29, 1985, and petitions for reconsideration, including environmental, energy, and public use concerns, must be filed by May 7, 1985 with: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

A copy of any petition filed with the Commission should be sent to applicant's representatives:

Lawrence H. Richmond, Suite 2204, 100 North Charles Street, Baltimore, MD 21201

Peter J. Shultz, P.O. Box 6419, Cleveland, OH 44101.

If the notice of exemption contains false or misleading information, use of the exemption is void *ab initio*.

A notice to the parties will be issued if use of the exemption is conditioned upon environmental or public use conditions.

Decided: April 8, 1985.

By the Commission, Heber P. Hardy, Director, Office of Proceedings.

James H. Bayne, Secretary.

FR Doc. 85-9236 Filed 4-16-85; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-31 (Sub-21X)]

Grand Trunk Western Railroad Co.; Discontinuance of Service in Saginaw County, MI; ¹ Corrected Notice of Exemption

On March 4, 1985, Grand Trunk Western Railroad Company (GTW) filed a notice of exemption under 49 CFR Part 1152 Subpart F—*Exempt Abandonments*, to abandon a portion of former Michigan Central Saginaw Branch railroad line extending between milepost 92.5 and milepost 98.8, a distance of approximately 6.1 miles, in Saginaw County, MI.

The notice of exemption served March 29, 1985, inadvertently misdescribed the type of action that would exempt. The notice of exemption described the line as one to be abandoned by (GTW), but did not reflect that a portion of this line is used by The Chesapeake and Ohio Railway Company (C&O) under a trackage rights agreement and that portion has been offered for sale to C&O.

Since GTW has not described the portion that may be sold to C&O, the extent of the remaining portion that will be abandoned can not be determined. Accordingly, the notice of exemption is corrected to reflect the fact that the exemption involves only a discontinuance of service for the entire 6.1 mile line. At such time that Grand Trunk determines the portion of the line which C&O will acquire, it can file a notice of exemption to abandon the remainder.

GT has certified (1) that no local traffic has moved over the line for at least 2 years, (2) the line does not handle overhead traffic, and (3) no formal complaint filed by a user of rail service on the line (or by a State or local governmental entity acting on behalf of such user) regarding cessation of service on the line either is pending with the Commission or has been decided in favor of the complainant within the 2-year period preceding this notice. The Public Service Commission or equivalent agency in the State of Michigan has been notified. See *Exemption of Out of Service Rail Lines*, 366 I.C.C. 885 (1983).

As a condition to use of this exemption, any employee affected by the abandonment shall be protected pursuant to *Oregon Short Line R. Co.—Abandonment—Goshen*, 360 I.C.C. 91 (1979).

¹ Previously entitled *Grand Trunk Western Railroad Company—Abandonment—In Saginaw County, MI*.

The exemption will be effective on May 17, 1985 (unless stayed pending reconsideration). Petitions to stay the effective date of the exemption must be filed by April 29, 1985, and petitions for reconsideration, including environmental, energy, and public use concerns, must be filed by May 7, 1985, with: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

A copy of any petition filed with the Commission must be sent to applicant's representatives: John C. Danielson, Grand Trunk Western Railroad Company, 131 West Lafayette Boulevard, Detroit, MI 48226.

If the notice of exemption contains false or misleading information, the use of the exemption is void *ab initio*.

A notice to the parties will be issued if use of the exemption is conditioned upon environmental or public use condition.

Decided: April 11, 1985.

By the Commission, Heber P. Hardy, Director, Office of Proceedings.

James H. Bayne,

Secretary.

[FR Doc. 85-9239 Filed 4-16-85; 8:45 am]

BILLING CODE 7035-01-M

[Finance Docket No. 30639]

Louisiana & Arkansas Railway Co.; Trackage Rights Exemption; Illinois Central Gulf Railroad Co. and New Orleans Terminal Co.; Exemption

On March 18, 1985, Louisiana & Arkansas Railway Company (L&A) filed a notice of exemption under 49 CFR 1180.4(g) to relocate a line of railroad.

L&A and Illinois Central Gulf Railroad Company (ICG) operate parallel tracks for a considerable distance in Jefferson Parish, LA. The close proximity of these tracks to each other has resulted in duplicate grade crossings and traffic congestion on a major thoroughfare. To alleviate this problem, the Louisiana Department of Transportation and Development reached an agreement with L&A, ICG, and New Orleans Terminal Company (NOT) that contemplates removal of certain grade crossings and the consolidation of the operations of L&A and ICG on certain lines of ICG and NOT. In particular, L&A will (1) abandon (a) 4,060 feet of its line between milepost 855.60 and milepost 856.37 and (b) 28,275 feet of its line extending between the westerly right-of-way line of Worth Street at

milepost 856.78 and the easterly right-of-way lines of Turnbull Drive at milepost 862.14; (2) acquire trackage rights (a) over the line of ICG between Alliance Avenue near Frellsen and East Bridge Junction in Shrewsbury, a distance of approximately five miles in Jefferson Parish, and (b) over those portions of the lines of NOT in Shrewsbury between milepost 0.05-A and milepost 0.90-A and over that portion of NOT Track 1-9 between the southwesterly switching point of this line and the point of connection with L&A, a distance of approximately 352 feet; and (3) construct (a) two connections between its line and the line ICG, and (b) certain tracks on an easement of NOT.¹

Joint projects involving the relocation of a line of railroad which does not disrupt service to shippers are categorically exempt from 49 U.S.C. 11343. See 49 CFR 1180.2(d)(5). In *D.T. & L.R.—Trackage Rights*, 363 L.C.C. 878 (1981), the Commission determined that line relocations embrace trackage rights transactions like the one involved here. The relocation of L&A's line does not affect any shippers. In fact, the only shipper located on the existing line has not shipped any traffic within the past two years and has advised L&A that it does not oppose relocation of the line. Accordingly, the relocation of the L&A line meets the criteria of 49 CFR 1180.2(d)(5).

As a condition to the use of this exemption, L&A has proposed that any employees affected by the transaction be protected by the conditions set forth in *Norfolk and Western Ry. Co.—Trackage Rights—BN*, 354 L.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.—Lease and Operate*, 360 L.C.C. 653 (1980). However, since the relocation project involves not only trackage rights but an incidental abandonment as well, we also must impose the conditions set forth in *Oregon Short Line R. Co.—Abandonment—Goshen*, 360 L.C.C. 91 (1979). Together these conditions satisfy the statutory requirements of 49 U.S.C. 10505(g)(2).

Decided: April 9, 1985.

By the Commission, Heber P. Hardy,
Director, Office of Proceedings.

James H. Bayne,
Secretary.

[FR Doc. 85-9237 Filed 4-16-85; 8:45 am]

BILLING CODE 7035-01-M

¹ Transactions that fall into one of the exempt categories in 49 CFR 1180.2(d) are exempt from prior approval under 49 U.S.C. 11343. If elements of the transaction also require approval under other sections of 49 U.S.C. Subtitle IV, a separate authority or exemption under 49 U.S.C. 10505, from those sections must be obtained. A separate decision will follow concerning the construction phase of the transaction.

DEPARTMENT OF JUSTICE

Lodging of Consent Decree; Chrysler Corp.

In accordance with Departmental policy, 28 CFR 50.7, notice is hereby given that on April 4, 1985 a proposed consent decree in *United States v. Chrysler Corporation*, Civil Action No. 85-CV-71482-DT was lodged with the United States District Court for the Eastern District of Michigan, Southern Division. The United States simultaneously filed a complaint against the Chrysler Corporation which alleges violations of Section 307 of the Clean Water Act resulting from the failure of three of Chrysler's vehicle assembly plants to meet the Act's electroplating pretreatment standards by the June 30, 1984 compliance date. The three plants are: the Warren Plant, located at 21500 Mound Road, Warren, Michigan; the Jefferson Avenue Plant, located at 12220 East Jefferson Avenue, Detroit, Michigan; and the Newark Plant, located at 550 South College Avenue, Newark, Delaware.

The complaint seeks injunctive relief to require Chrysler to comply with the applicable pretreatment standards at the three assembly plants and to submit a detailed plan for bringing the plants into compliance. The complaint also seeks a court order requiring Chrysler to pay civil penalties for violation of the standards.

The key terms of the proposed consent decree are as follows:

1. Chrysler agrees to pay a civil penalty of \$1.5 million for failure to bring the three plants into timely compliance with the applicable pretreatment standards;
2. Chrysler agrees to construct permanent treatment systems, and to demonstrate and achieve final compliance with the standards, by July 15, 1985—subject to stipulated penalties for noncompliance;
3. Chrysler agrees to take specified interim measures to reduce heavy metal discharges prior to achieving final compliance; and
4. Chrysler agrees to sample and monitor for compliance three times per week at each plant over the live of the decree.

The Department of Justice will receive comments relating to the proposed consent decree for a period of thirty (30) days from the date of this publication. Comments should be addressed to the Assistant Attorney General of the Land and Natural Resources Division, Department of Justice, Washington, D.C. 20530. All comments should refer to

United States v. Chrysler Corporation,
D.J. Ref. 90-5-1-1-2239.

The proposed consent decree may be examined at the following offices of the United States Attorney and the Environmental Protection Agency (EPA):

EPA Region III

Contact: Shanna Halpern, Assistant Regional Counsel, Office of Regional Counsel, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, PA 19107, (215) 597-3439.

EPA Region V

Contact: Linda Szempruch, Assistant Regional Counsel, Office of Regional Counsel, U.S. Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, IL 60604, (312) 886-6831

United States Attorneys Office

Contact: Geneva Halliday, Assistant United States Attorney, Eastern District of Michigan, 817 Federal Building, 231 West Lafayette, Detroit, Michigan 48207, (313) 226-2163

Copies of the consent decree may also be examined at the Environmental Enforcement Section, Land and Natural Resources Division, United States Department of Justice, Room 1517, Ninth Street and Pennsylvania Avenue, NW., Washington, D.C. 20530. A copy of the proposed consent decree may be obtained by mail from the Environmental Enforcement Section, Land and Natural Resources Division of the Department of Justice. In requesting a copy of the decree, please enclose a check in the amount of \$2.80 payable to Treasurer of the United States.

F. Henry Habicht II,
Assistant Attorney General, Land and Natural Resources Division.

[FR Doc. 85-9207 Filed 4-16-85; 8:45 am]

BILLING CODE 4410-01-M

DEPARTMENT OF LABOR

Office of Pension and Welfare Benefit Programs

[Application No. D-5324, et al.]

Employee Benefit Plans; Proposed Exemptions; Operating Engineers Pension Trust et al.

AGENCY: Pension and Welfare Benefit Programs, Labor.

ACTION: Notice of Proposed Exemptions.

SUMMARY: This document contains notices of pendency before the Department of Labor (the Department)

of proposed exemptions from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1954 (the Code).

Written Comments and Hearing Requests

All interested persons are invited to submit written comments or requests for a hearing on the pending exemptions, unless otherwise stated in the Notice of Pendency, within 45 days from the date of publication of this **Federal Register** Notice. Comments and requests for a hearing should state the reasons for the writer's interest in the pending exemption.

ADDRESS: All written comments and requests for a hearing (at least three copies) should be sent to the Office of Fiduciary Standards, Pension and Welfare Benefits Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20216. Attention: Application No. stated in each Notice of Pendency. The applications for exemption and the comments received will be available for public inspection in the Public Documents Room of Pension and Welfare Benefit Programs, U.S. Department of Labor, Room N-4677, 200 Constitution Avenue, NW., Washington, D.C. 20216.

Notice to Interested Persons

Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department within 15 days of the date of publication in the **Federal Register**. Such notice shall include a copy of the notice of pendency of the exemption as published in the **Federal Register** and shall inform interested persons of their right to comment and to request a hearing (where appropriate).

SUPPLEMENTARY INFORMATION: The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section 4975(c)(2) of the Code, and in accordance with procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, these notices of pendency are issued solely by the Department.

The applications contain representations with regard to the

proposed exemptions which are summarized below. Interested persons are referred to the applications on file with the Department for a complete statement of the facts and representations.

Operating Engineers Pension Trust (the Pension Plan) and Operating Engineers Journeyman and Apprenticeship Training Trust (the Training Plan; together, the Plans) Located in Los Angeles, California

[Application Nos. D-5324 and D-5325]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted the restrictions of section 406(a) and 406(b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (D) of the Code shall not apply to the proposed use by the Training Plan of a parcel of real property (the Property) owned by the Pension Plan, under the terms described in this notice of proposed exemption, provided such terms are at least as favorable to the Plans as those obtainable in an arm's-length transaction with unrelated parties.

Summary of Facts and Representations

1. The Pension Plan is a collectively bargained multiemployer Pension Plan with approximately 28,760 participants. The Training Plan is a collectively bargained multiemployer employee welfare plan with approximately 13,181 participants. As of June 30, 1984, the Pension Plan had assets of approximately \$566 million, and the Training Plan has assets of approximately \$2,330,161 as of August 31, 1984.

2. The Training Plan pays contributions to the Pension Plan on behalf of employees of the Training Plan pursuant to a written agreement providing for such contributions. The applicants acknowledge that as a result, the Training Plan is a party in interest with respect to the Pension Plan under section 3(14) (C) of the Act as an employer whose employees are covered by the Pension Plan. Therefore, exemptive relief from the restrictions of section 406(a) of the Act is necessary for the subject transaction, as well as relief from the restrictions of section 406(b)(2) [see representation 9 below].

3. The Property, which is owned by the Pension Plan, consists of

approximately 4,367 acres of primarily undeveloped real property known as Rancho Dos Vientos, located near Thousand Oaks, California. The Pension Plan acquired the Property for \$12 million on April 12, 1982. Upon acquisition of the Property, the Pension Plan retained the services of Haaland & Associates (Haaland), an independent civil engineering firm, to represent the Pension Plan's interests in relation to the governmental authorization of specific plans for use of the Property, with particular regard to the anticipated annexation of a substantial portion of the Property by the City of Thousand Oaks (the City). The Pension Plan also obtained the professional services of an architect to provide architectural consultation in support of the land planning. The Plan further retained special counsel on matters relating to the annexation of the Property and approval of specific use plans by the City.

4. The Plans now wish to enter into an agreement whereby the Property is to be used as a training site for apprentices and journeymen participating in the Training Plan program. The term of the agreement will be for one year, and the agreement shall be automatically renewed from year to year thereafter unless one Plan gives the other 90 days written notice prior to the end of the term. In addition, either Plan may terminate the agreement on 90 days written notice to the other Plan.

5. The use of the Property shall be rent-free to the Training Plan. In exchange, the Pension Plan will be receiving improvements on the Property. The agreement calls for the Training Plan to perform such improvements as building roads, excavation of earth for drainage channels and sewers, grading of earth, construction of equestrian trails and recreational facilities, and construction of tunnels. The Training Plan shall pay all ordinary operating expenses incurred in the undertaking of training projects on the Property, except the costs of special materials or services identified by the Training Plan and approved by the Pension Plan.

6. The applicants represent that preserving and enhancing the value of such a substantial real estate parcel as the Property involves comprehensive planning and coordination with other affected parties. Such activities have necessarily been conducted continuously since the Pension Plan acquired the Property, and as a result, the Planning Staff of the City is presently reviewing a proposed preliminary plan for use and development of the Property. The City is

also in the process of preparing an Environmental Impact Report concerning the potential uses and development of the Property. Formal review and public hearings regarding planned uses of the Property are expected to begin shortly. In due course, the City is expected to approve a specific plan and pre-zone the Property, subject to annexation, and finally annex approximately 2,346 acres of the Property which are within the sphere of influence of the City sometime in 1985 or early 1986.

7. The specific uses of the Property likely to be authorized by the City are expected to include approval of development of certain parcels as "affordable housing", according to the terminology of local government land planning authorities. Applicable planning and zoning regulations allow development of property as "affordable housing" to be exempted from much of the time-consuming process required to obtain building permits. Accordingly, the Pension Plan believes that the City will issue "affordable housing" exemptions applicable to certain parts of the Property in about April, 1985, which should enable preliminary work relating to site preparation of those parcels to begin at that time. Specifically, grading and excavating to prepare roads for access to the "affordable housing" parcels would provide substantial projects within the capability of Training Plan apprentices and trainees.

8. The Training Plan has in past years found appropriate training projects by responding to requests to repair and maintain fire roads, to repair storm damage to camp grounds of the Boy Scouts of America, by grading or repairing fields for Little League Baseball or public parks, and similar kinds of endeavors. Among the current projects undertaken by the Training Plan are the building, repairing and maintenance of fire roads providing access to wilderness areas under a cooperative agreement with the Kern County (California) Fire Department. Since 1977, the Training Plan has maintained fire roads and conducted related training activities on property owned by Lockheed Properties, Inc., under a cooperative agreement with the owner. These training projects and other current similar ones are comparable to the subject training projects. The applicants represent that the proposed training projects on the Property would provide greater variety, magnitude and continuity of training projects than any current site. All projects undertaken by the Training Plan pursuant to the subject

agreement will be projects needed by the Pension Plan in connection with the overall governmentally-approved plan of development for the Property.

9. The Pension Plan has a board of 14 trustees, and the Training Plan has a board of 12 trustees. There are 7 trustees who are common to the two Plans. However, for purposes of the subject transaction, the Pension Plan has appointed an independent fiduciary, Buss-Shelger Associates (BSA). BSA represents that it is qualified by training and experience in the field of real estate management and development, particularly in Southern California. BSA acknowledges its status as a fiduciary to the Pension Plan under the Act, and it understands and accepts its duties, liabilities and responsibilities as such. The trustees of the Training Plan will represent that Plan in the subject transaction.

10. BSA has reviewed the proposed agreement on behalf of the Pension Plan, and represents that entering the agreement would be in the best interests of the Pension Plan and its participants and beneficiaries. In making this determination, BSA has considered the general investment objectives of the Pension Plan and has determined that the agreement is reasonably designed to further the purposes of the Pension Plan, taking into consideration the risk of loss and the opportunity for gain or other return associated with entry into the agreement. In addition, BSA has considered a report prepared by Haaland of cost estimates for the 2,145 dwelling units to be developed by the Pension Plan on the Property in the initial development stage. Haaland has determined that the equipment and labor savings to the Pension Plan of entering into the subject agreement with the Training Plan would be \$12,522,000.

11. BSA further represents that it will monitor the performance of the parties to the agreement to determine whether the agreement is desirable and beneficial to the Pension Plan on a continuing basis. In performing such duties, BSA shall consider all relevant facts and circumstances, including the long-term advantages of the agreement and the investment objectives of the Pension Plan with respect to the Property. If at any time BSA determines that the continuation of the agreement may no longer be in the interest of the Pension Plan, and the agreement cannot be modified to BSA's satisfaction, then BSA shall terminate the agreement in accordance with its terms.

12. In summary, the applicants represent that the proposed transaction

meets the criteria of section 408(a) of the Act because: (1) The Training Plan will benefit by the use of the Property for training purposes at no cost to the Training Plan; (2) the Pension Plan will benefit by the improvements which will be performed on the Property at no charge to the Pension Plan; (3) BSA, the Pension Plan's independent fiduciary, has determined that the transaction is in the best interests of the Pension Plan; and (4) BSA will monitor the transaction and make any decision to terminate the transaction if it believes such action would be in the best interests of the Pension Plan.

Notice to Interested Persons: Within 30 days of the publication of this proposed exemption in the **Federal Register**, notice of the proposed exemption will be provided to all interested persons in the manner agreed upon by the applicants and the Department. Comments and hearing requests are due within 60 days of the date of publication.

For Further Information Contact: Gary Lefkowitz of the Department, telephone (202) 523-8881. (This is not a toll-free number.)

Simpson Manufacturing Co., Inc. Profit Sharing Plan (the Plan) Located in San Leandro, California

[Application No. D-5544]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted the restrictions of sections 406(a), 406(b)(1) and (b)(2) and 407(a) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to 1) the leasing of real property located at 1450-1532 Doolittle Drive, San Leandro, California (the Property) by the Plan to Simpson Strong Tie Company, Inc. (Strong-Tie) and Simpson Structures, Inc. (Structures), under the terms described in this notice of proposed exemption, provided such terms are not less favorable to the Plan than those obtainable in an arm's-length transaction with an unrelated party; and 2) the continuation beyond June 30, 1984 of a loan to the Plan by Bank of America, N.T. & S.A. (the Bank), provided the terms of the loan are not less favorable to the Plan than those obtainable in an arm's length transaction with an unrelated party.

Effective Dates: If this proposed exemption is granted, it will be effective from December 4, 1984 through December 31, 1987 as to the lease, and effective July 1, 1984 as to the loan.

Summary of Facts and Representations

1. The Plan is a profit sharing plan which had 109 participants and approximately \$5,775,200 of total assets as of December 31, 1983. Simpson Manufacturing Co., Inc. (Simpson), the Plan sponsor, and its wholly owned subsidiaries, Strong-Tie and Structures, are manufacturers of pre-fabricated housing products.

2. In December, 1972, the Plan purchased the Property located at 1450-1532 Doolittle Drive, San Leandro, California for \$327,799.50, subject to a \$260,000 note and deed of trust. The \$260,000 was loaned (the Loan) to the Plan by the Bank, which was also the Plan trustee. Also in December, 1972, the Plan entered into a 10 year lease agreement with Simpson. Simpson agreed to lease the Property from the Plan at an initial rate of \$4,000 per month, to be adjusted triennially in accordance with a specific Consumer Price Index (CPI) factor. Effective December 1, 1982, the lease was renewed with Strong-Tie and Structures as lessees, at a total monthly lease rate of \$13,500, to be adjusted December 1, 1985 and biennially thereafter in accordance with a specific CPI factor. The lease was modified on November 21, 1984 to provide that the biennial rent adjustments shall be to the higher of the change in the CPI or the fair market rental value of the Property as determined by independent appraisal. The rent revision shall be the higher of the two, but not less than the current rent. The applicants represent that the December, 1972 lease and the December, 1982 renewal thereof were statutorily exempt until June 30, 1984 from the prohibitions of sections 406 and 407(a) of the Act and section 4975 of the Code by virtue of sections 414(c)(2) and 2003(c)(2)(B) of the Act.¹

3. The applicants have requested an exemption to permit the continued leasing of the Property by the Plan to Strong-Tie and Structures. In this regard, the Plan has appointed an independent fiduciary, Mr. William E. Figara (Mr. Figara), president of the Alpha Capital Company, an independent investment advisor located in Emeryville,

California. Mr. Figara represents that he has directed the investment of a portion of the assets of the Plan for six years and is therefore familiar with the operation of the Plan and its investment portfolio. In addition to the Plan, Mr. Figara directs the investment of assets of numerous other qualified plans and is aware of the duties and responsibilities of fiduciaries under the Act. Mr. Figara represents that he has not been involved with the subject lease in the past, and has no relationship with Simpson and its affiliates other than as described herein. Mr. Figara has been appointed as independent fiduciary with respect to the lease transaction as of December 4, 1984.

4. Mr. Figara represents that the continuation of the lease would be appropriate for the Plan and in the best interests of its participants and beneficiaries. He has based this determination on an examination of the rate of return generated by the Property over a five year period. Over that time, the Property has produced an average annual return of 39.3% to the Plan. Mr. Figara believes that, based on the monthly rentals being paid to the Plan, the appreciation history of the Property, and the potential future increases in value of the Property, the Property will continue to be an excellent Plan investment. Mr. Figara further represents that he will monitor the lease during the period of its continued existence in order to make sure that it continues to be in the best interests of Plan participants and beneficiaries. Mr. Figara is authorized to select the independent appraiser who will determine the fair market rental value of the Property biennially. Mr. Figara represents that he will take whatever steps are appropriate to enforce the Plan's rights under the lease.

5. The Property currently represents approximately 29.5% of the Plan's assets. The applicants represent that for the four years prior to 1983, the Property represented between 17.4% and 23.5% of the Plan's assets. However, due to an extremely high rate of appreciation during 1983, the Property now constitutes a higher percentage of the Plan's assets, i.e., 29.5%. Mr. Figara represents that it is still in the Plan's best interest to retain ownership of the Property despite the current percentage of Plan assets represented by the Property. The applicants represent that if the temporary prohibited transaction exemption for the lease proposed herein is granted, the fair market value of the Property will be reduced to 25% or less of total Plan assets by December 31, 1987. The applicants represent that on or

before December 31, 1987, the Property will be sold by the Plan or otherwise disposed of, or an additional exemption to continue the arrangement beyond December 31, 1987 will be sought.²

6. Mr. Steven Chan, M.A.I. (Mr. Chan), an independent real estate appraiser in San Leandro, California, has represented that the fair market rental value of the Property as of July 1, 1984 was \$256,350 annually, or \$21,362.50 per month. Since that amount is greater than the \$13,500 monthly rent currently called for in the lease, the difference of \$7,862.50 per month will be paid to the Plan, together with interest at a rate determined by Mr. Figara, retroactively, for the period commencing July 1, 1984. The lease was amended to provide for the increased rental per Mr. Chan's appraisal of the fair market rental value of the Property. In addition, any excise tax which is due as a result of the lease arrangement for the period from July 1, 1984 to December 4, 1984, the effective date of the exemption for the lease, will be paid by the applicants within 60 days of the date of the granting of the exemption proposed herein.

7. The applicants have also requested an exemption to permit the continuation of the Loan beyond June 30, 1984. The applicants represent that the Loan was statutorily exempt until June 30, 1984 by reason of section 414(c)(1) and 2003(c)(2)(A) of the Act.³ The Loan was for \$260,000, at 8 1/4% fixed interest, payable at the rate of \$2,525 per month over a period of 179 successive months until January 1, 1988, when the entire balance of principal and interest becomes due. The applicants represent that the Bank is a directed trustee, and the decision to enter the Loan transaction was made on behalf of the Plan by its Administrative Committee. The Committee consists of individuals who are independent of the Bank.

8. The applicants represent that the Loan was made at the Bank's going rate for such loans at the time of the transaction. As of June 30, 1984, the outstanding balance on the Loan was \$92,988.76. The Bank represents that as of June 30, 1984, its going rate for adjustable rate loans was between 14 1/4% and 15 1/4%. The Plan Administrative Committee represents that the continuation of the Loan beyond

² The Department provides no assurance that such exemption, if sought at such time, will be granted.

³ The Department expresses no opinion as to whether the Loan was statutorily exempt until June 30, 1984 from the prohibitions of sections 406 and 407(a) of the Act and section 4975 of the Code by reason of sections 414(c)(1) and 2003(c)(2)(A) of the Act.

¹ The Department expresses no opinion as to whether the December, 1972 lease or the renewal thereof were statutorily exempt until June 30, 1984 from the prohibitions of sections 406 and 407(a) of the Act and section 4975 of the Code by reason of sections 414(c)(2) and 2003(c)(2)(B) of the Act.

June 30, 1984 is clearly in the Plan's best interest as the rate for the Loan is significantly less than the rate the Plan would pay for a new loan. In addition, Mr. Figara represents that it is in the Plan's best interest to continue the Loan under its present terms. The Committee has monitored the Loan throughout its duration, and will continue to monitor the Loan to ensure that the Loan remains in the best interest of the Plan and its participants and beneficiaries.

9. In summary, the applicants represent that the subject transactions meet the criteria of section 408(a) of the Act because: (1) The Plan's independent fiduciary, Mr. Figara, has determined that the lease is appropriate for the Plan and in the Plan's best interest; (2) Mr. Figara will monitor the lease and take whatever action is necessary to enforce the Plan's rights; (3) the lease provides for the fair market rental value of the Property as determined by an independent appraiser; (4) the Plan's Administrative Committee, which is independent of the Bank, approved the Loan and will continue to monitor it to determine that it remains in the Plan's best interest; and (5) the Loan is at a rate considerably advantageous to the Plan in comparison to current rates.

For Further Information Contact: Mr. Gary Lefkowitz of the Department, telephone (202) 523-8881. (This is not a toll-free number.)

First Citizens National Bank, Tupelo, Mississippi, Investment Funds for Qualified Employee Benefit Plans—Funds A and B (the Funds) Located in Tupelo, Mississippi

[Application No. D-5560]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted the restrictions of section 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to the past sale by the Funds of all mortgage notes (the Notes) held by First Citizens National Bank, Tupelo, Mississippi (the Bank) as trustee of the Funds, to the Bank, provided that the sales price was no less than the greater of the fair market value of the Notes or the unpaid principal amount plus accrued interest.

Effective Date: The effective date of this proposed exemption, if granted, is March 21, 1984.

Summary of Facts and Representations

1. The Funds are common trust funds under the trusteeship of the Bank. As of June 21, 1984, 64 employee benefit plans were participants in the Funds. The Bank is responsible for the investment of the assets of the Funds. Among the assets of the Funds were the Notes. The Notes are 46 mortgage notes originated by the Funds with interest rates ranging from 8% to 16%.

2. The applicant represents that in August, 1983, the Comptroller of the Currency (the Comptroller) examined the Bank's trust department. The examiners questioned the Bank's valuation of the Notes at their book value (i.e. the unpaid principal balance of the Notes) rather than at their "fair value" as required by 12 CFR 9.18(b)(1). The applicant further represents that the Bank inquired of the Comptroller as to the permissible circumstances under which the Notes might be purchased by the Bank, proposing that the Bank obtain a prohibited transaction exemption from the Department for such a purchase.

3. On January 30, and 31, 1984, the Funds were examined by the Department's Nashville Area Office (the Area Office). By letter dated February 17, 1984, the Area Office questioned the Bank's valuation of the Notes at their book values rather than their "current value". The Area Office agreed to the Bank's proposal to purchase the Notes from the Funds at a price equal to the greater of the fair market value or unpaid principal balance plus accrued interest of the Notes, and requested that the Bank immediately proceed with the purchase.

4. On February 29, 1984, the Bank advised the Area Office that it would proceed with the purchase and that it was so informing the Comptroller by letter of the same date. The Bank further advised the Area Office that it requested the Comptroller to submit any negative comments concerning the proposed purchase by March 16, 1984. On March 20, 1984, the Bank, having received no negative comments from the Comptroller, calculated the fair market value and unpaid balance of each Note. The aggregate fair market value of the Notes was \$2,997,706.28 as of that date. The Bank arrived at this amount by calculating the present value of each Note based upon the stream of income payments being received on each Note until maturity. In the case of a Note with a balloon payment, the present value of the balloon balance at maturity was added to the present value of the stream

of income payments. The calculations were based on rates of U.S. Treasury securities with maturity dates coinciding with the balloon payment or final maturity payment dates. The applicant represents that this formula was approved by the Bank's independent auditors prior to March 20, 1984.

5. On March 21, 1984, the Bank purchased the Notes for \$3,070,801.02 in cash, representing the unpaid balance of the Notes plus accrued interest. The purchase price was \$73,094.74 higher than the fair market value of the Notes as determined by the Bank. The applicant represents that the Bank purchased the Notes from the Funds prior to the receipt of a prohibited transaction exemption because the Area Office specifically advised the Bank that an exemption would not be required. By letter dated April 19, 1984, the Area Office advised the Bank that it appeared that the Bank had taken the corrective action suggested by the Area Office. The Area Office further advised the Bank that it had determined that an exemption was required. Accordingly, the Bank filed the above referenced application.

6. The applicant represents that one of the 46 Notes secures a loan that was made to F.M. Bush, III, a party in interest with respect to the Funds. The applicant further represents that Mr. Bush will pay all applicable excise taxes within 60 days of the granting of this proposed exemption. In addition, the applicant represents that no other loans were made to parties in interest with respect to the Fund.

7. In summary, the applicant represents that the sale of the Notes met the requirements of section 408(a) of the Act because: (a) The Funds received a price higher than the fair market value of the Notes; (b) the Bank purchased the Notes at the direction of the Area Office; and (c) the formula used to calculate the fair market value of the Notes was approved by the Bank's independent auditors.

For further information contact: David M. Cohen of the Department, telephone (202) 523-8671. (This is not a toll-free number.)

Smart Chevrolet Co. Employees' Profit Sharing Retirement Plan (the Profit Sharing Plan) and Smart Chevrolet Co. Employees Retirement Plan (the Retirement Plan) (collectively, the Plans) Located in Pine Bluff, Arkansas

[Application Nos. D-5669 and D-5670]

Proposed Exemption

The Department is considering granting an exemption under the

authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 16471, April 28, 1975). If the exemption is granted the restrictions of sections 406(a), 406(b)(1) and 406(b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of sections 4975(c)(1) (A) through (E) of the Code shall not apply to (1) the proposed loans (the Loans) by the Plans to Motors Finance Company (Motors), a party in interest with respect to the Plans, provided that the terms and conditions of the Loans are at least as favorable as those which the Plans could receive in similar transactions with an unrelated party; and (2) the guarantee of the Loans by Smart Chevrolet Company (Smart Chevrolet), and the individual partners of Motors.

This notice of pendency was originally published in the *Federal Register* on March 1, 1985 (50 FR 8416). However, because of material omissions in the facts and representations in the original notice this notice of pendency is being republished as follows:

Summary of Facts and Representations

1. The Profit Sharing Plan is a profit sharing Plan which, as of March 30, 1984, had 54 participants and assets of \$945,588. The Retirement Plan is a defined contribution target benefit money purchase plan which as of March 30, 1984 had nine participants and assets of \$581,557. The Retirement Plan was terminated on January 1, 1978, and continues as a frozen plan. The sponsor of the Plans is Smart Chevrolet which is engaged in the sale of automobiles. Motors is engaged in the business of financing new and used cars which are sold by Smart Chevrolet. Certain of the principal owners of Smart Chevrolet are also the principal partners of Motors. The National Bank of Commerce of Pine Bluff (NBC) which is located in Pine Bluff, Arkansas is the trustee of the Plans (the Trustee). NBC is a subsidiary bank of the First Arkansas Bank Corporation (FABCO), a holding company, and has total assets of approximately \$218,000,000. Mr. Richard Smart (Mr. Smart), a 25% shareholder in Smart Chevrolet and a 5% partner in Motors, owns 42 shares of FABCO and is one of 18 directors of NBC. Mr. Smart represents that he will abstain from making any decisions in his capacity as director of NBC which will affect the business of Motors and Smart Chevrolet. The partners in Motors and the shareholders of Smart Chevrolet maintain personal deposits at NBC the average balance of which does not exceed \$2,500 and individual retirement

accounts the largest of which is less than \$10,000. The operating funds used by Motors and Smart Chevrolet are merged on a daily basis at NBC. The applicant represents that the daily balance concerning any line of credit or any investment account for NBC and Smart Chevrolet has not exceed \$200,000 over the past three months. Further, it is represented that the cumulative financial involvement of NBC with Motors and Smart Chevrolet and their respective partners and shareholders constitutes .1376% of the assets of NBC.

The First National Bank of Altheimer (FNBA), located in Altheimer, Arkansas will serve as the independent fiduciary on behalf of the Plans for the transactions which are the subject of this exemption request. Mr. J.P. Walt (Mr. Walt), president of FNBA, represents that none of the partners in Motors, the stockholders in Smart Chevrolet or the officers and directors of Smart Chevrolet Company are officers or directors of FNBA. In addition, Mr. Walt represents that none of these persons are stockholders of FNBA, except Felix Smart who owns 35 shares, which represents an ownership percentage of FNBA of .466%. Felix Smart owns a 15% partnership interest in Motors. The partners of Motors, the Smart Chevrolet, stockholders and officers and directors of Smart Chevrolet do not have any loans or accounts at FNBA, except a non-interest bearing checking account in the names of Mr. and Mrs. Felix Smart.

2. The applicant is requesting an exemption which will permit the Loans in an amount of up to 25% of the assets of each of the Plans. Each of the Plans will participate in the Loans on an equal percentage basis. For example, if Motors borrows 10% of the assets of the Profit Sharing Plan, it will also borrow 10% of the assets of the Retirement Plan. All Loans will bear interest at a rate which is two percentage points above the federal discount rate and will have a maturity of 90 days. The Loans will be secured by a perfected security interest in all installment sale contracts (Contracts) of Motors. If additional financing is needed to finance its business, Motors will have the right to have certain Contracts released but the Plans will always be secured by Contracts having a face value of at least 150% of the amount of the Loans. In addition, since Motors is a partnership, all of the partners are jointly and severally liable for the debts of the partnership, specifically including the Loans. The collective net worth of the partners of Motors as of December 31, 1983, was 1983, was \$4,927,256. All of the

Contracts also are with recourse against Smart Chevrolet, which has a net worth as of December 31, 1983 of \$1,421,114. The net worth of Motors as of the end of its most recent fiscal year, which was September 30, 1983, was \$359,059.31. In addition, the notes payable from Motors to the partners and related parties will be subordinated to the Loans. The amount of the notes payable to be subordinated as of December 31, 1983, was \$987,983. The net worth of the partners of Motors includes their respective interests in Motors, Smart Chevrolet, and the notes payable from Motors. As of March 31, 1984, Motors had 324 Contracts outstanding with balances totaling \$1,561,203, with an average balance of \$4,819 per Contract.

3. The applicant represents that the wide diversity of customers executing the Contracts significantly spreads the risk of the Plans. In selecting the customers for the Loans, NBC will monitor Motors to insure that it will continue to follow its current loan policy in financing vehicles, which includes obtaining a complete credit history for each prospective customer and analyzing the customer's credit history together with the terms of the loans. No loans will be made to persons who currently have a bankruptcy, loan default, or other credit problem. Depending on the use of the vehicle, a customer equity of from 10% to 30% will be required and maximum length of contracts will be 48 months on new and current used vehicles, 42 months on one year vehicles, 36 months on two and three year old vehicles, 30 months on four year old vehicles and 24 months on five year old or older vehicles. The applicant also represents that each purchaser is required to carry comprehensive insurance on the vehicle. A collector is employed full time by Motors and the applicant represents that strict supervision will be maintained daily in this area. All loan defaults will be paid off immediately by Smart Chevrolet after legal notice is given to the customer under Arkansas law. All of the Loans will be evidenced by a properly executed promissory note. The security interest in the installment sale contracts will be perfected by properly filed financing statements in conformity with the Uniform Commercial Code as adopted in Arkansas. NBC will verify that the installment sale contracts securing the indebtedness are at all times equal to or greater than 150% of the outstanding balances of the Loans. NBC will obtain periodic financial statements on Motors, Smart Chevrolet, and the partners of Motors. If there are any material decreases in the net worth

of any of the parties involved, NBC will liquidate the Loans at the next maturity date. In the case of a default, NBC will have the responsibility of enforcing all of the rights of the Plans. Further, if, as determined by NBC, a rate of two percentage points above the discount rate is not reflective of a reasonable rate of return on a 90 day investment of this type, the Loans will be liquidated at the next maturity date, or the yield on the Loans will be brought up to reasonable rate.

4. FNBA has reviewed the proposed transactions and represents that they will be in the best interests of the participants and beneficiaries of the Plans. In its analysis, FNBA represents that taking into account the quality and diversity of the Contracts, the net worth of Motors, the net worth of the partners in Motors, the net worth of Smart Chevrolet, and the subordination of the debts owed by Motors to its partners, the Loans are extremely well collateralized and the risk of loss to the Plans almost non-existent. As to liquidity and the rate of return to the Plans, the current investment philosophy of the Plans is to make secure short term investments with fixed yields. FNBA notes that the Loans will have a 90 day maturity. This gives liquidity to the Plans and will enable them to shift their investments away from the Loans in a short period of time if that is determined to be appropriate. FNBA represents that based on the short maturity of the Loans and almost complete lack of risk of loss, FNBA would consider a rate of return equal to two percentage points over the discount rate an appropriate rate of return. Considering the discount rate from a historical point of view, a rate of return which is two percentage points over the discount rate would have yielded a premium over 90 day certificates of deposits from 0 to 200 basis points in recent years. In the event the discount rate should lag behind increases in interest rates, the Plans can liquidate all or any part of the Loans in a period of 90 days or less. In addition, FNBA represents that it would make the Loans on the same terms, including the interest rate.

5. In summary, the applicant represents that the Loans will satisfy the criteria of section 408(a) of the Act as follows: (1) FNBA, the independent fiduciary of the Plans, represents that the Loans will be in the best interests of the participants of the Plans; (2) the Loans will be short term loans limited to 25% of the assets of the Plans; (3) NBC, the Trustee, will monitor the Loan program on behalf of the Plans; (4) the Loans will be secured by the Contracts,

by the guarantees of Smart Chevrolet, Motors, and the partners of Motors, and (5) the Plans will receive a fair market rate of return on the Loans.

For further information contact: Ms. Angelena C. Le Blanc of the Department, telephone (202) 523-8881. (This is not a toll free-number.)

Farmers National Bank of Webster City Profit Sharing Plan (the Plan) Located in Webster City, Iowa

[Application No. D-5909]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted the restrictions of section 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to the proposed purchase of participations (the Participations) in loans (the Loans) by the Plan for Commercial State Bank of Pocahontas, Iowa (Commercial) a party in interest with respect to the Plan, for a period of five years from the date of a grant of this proposed exemption, provided that the terms of the transactions are not less favorable to the Plan than the terms generally available in arm-length transactions between unrelated parties.

Summary of Facts and Representations

1. The Plan is not a profit sharing plan with 35 participants. The Plan's assets totaled \$872,057.55 as of October 31, 1984. The trustee (the Trustee) of the Plan is Valley National Bank of Des Moines, Iowa.

2. The Trustee administers nearly 110 tax qualified employee benefit plans with over \$70,000,000 in assets and has experience in administering a wide variety of assets, including loans, in the portfolios of such plans. The Trustee represents that none of the parties to the transaction, or any of the other parties in interest with respect to the Plan, has any relationship with the Trustee as owner, director or officer. Farmers National Bank of Webster City (the Employer) and Commercial maintain deposit account with the Trustee, in the aggregate totalling 0.47% of the Trustee's deposits.

3. The Plan proposes to purchase the Participations from Commercial, the originator of the Loans. In turn, Mr. Lenus Schramm (Mr. Schramm), the borrower, uses the Loan proceeds for

the purpose of purchasing feeder cattle. The cattle will be maintained at a feedlot owned by Poky Feeders, Inc. (Poky), Scott City, Kansas.

4. Commercial is a party in interest because Rodney Amlie (Mr. Amlie) is the majority owner of both the Employer and Commercial. The Trustee represents that Mr. Amlie and Mr. Schramm each own minority interests in Poky, and that their combined ownership of Poky is less than 50%.

5. The Loans will mature in 120 to 165 days and will be secured by the cattle purchased with the Loan proceeds (the Collateral). Interest rates will be set by Commercial at then current market rates, which the Trustee represents are currently 14%. Principal and interest will be paid at the time a Loan matures. The Trustee represents that the Collateral will equal at least 200% of the face value of the Plan's Participation in a Loan at the time of closing and throughout the term of the Loan. If the value of the Collateral falls below 200% of the face value of the Participation, the Trustee will have the option to require Mr. Schramm to pledge additional collateral sufficient to maintain 200% collateralization of the Participation or to require Commercial to purchase at face value plus accrued interest a sufficient portion of the subject Participation to cause the Collateral to equal or exceed 200% of the Participation.

6. The Trustee represents that its policy is for the Plan to purchase no more than a 25% Participation in any one Loan, and in no event will it ever acquire a 50% or more Participation in any one Loan. Immediately after the purchase of any Participation, no more than 10% of the fair market value of the Plan's assets will be invested in Participations.

7. Commercial will process, administer, and collect all Loans, and will then transfer payments of principal and interests to the Plan. In the event of a default, the Plan will have first priority to proceeds from disposition of the Collateral. The Trustee will have the authority to declare a default and take all actions necessary to protect the Plan's interests. The Plan will pay no fee or commission with respect to the purchase of a Participation or the servicing of a Loan.

8. The Plan will be named as the first or primary lienholder in the security agreement between Commercial and Mr. Schramm and in the UCC-1 financing statement. In addition, Commercial will enter into an agreement with the Plan subordinating its rights to the Collateral in favor of the Plan.

9. In order to determine the value of the Collateral the Trustee will obtain a price quote from the Dodge City, Kansas office of the U.S. Department of Agriculture for the same type of cattle on the date a new Loan is effected and will obtain similar quotes on a weekly basis to ensure that the Collateral remains at least equal to 200% of the Participation.

10. Before approving the Plan's purchase of a Participation in a Loan from Commercial, the Trustee will determine that: (a) Mr. Schramm is credit-worthy at the time of the transaction based upon current financial statements; (b) the interest rate is at least the current fair market rate; (c) the rate of return will exceed the return on Treasury investments of comparable maturity by at least 400 basis points; (d) the investment will not cause the aggregate investment in Participations to exceed 10% of the fair market value of the Plan's assets at the time of purchase; and (e) that all necessary representations and conditions of this proposed exemption including representations that the status and relationships of all parties have not materially changed, have been received.

11. The Trustee represents that it will make the decision of how much to invest in a Participation solely on the basis of the Plan's investment portfolio strategy and current needs in light of such strategy.

12. The Trustee represents that the Plan's purchase of Participations is not part of an arrangement whereby a Loan to Mr. Schramm would be contingent on the Plan's purchase of a Participation in that or any other Loan.

13. The Trustee represents that the Participations are good investment for the Plan: (a) The interest rate on the Loans will be at least 400 basis points higher than the return on certificates of deposit or Treasury bills of like maturity; (b) the current 14% return compares favorably with the 11.27% return on a pooled fixed income fund which, along with new contributions, would be the source of funds for the purchase of the Participations; (c) the purchase of Participations allows further diversification of the Plan's portfolio; (d) the Plan's investment will be protected in that the Collateral will be at least 200% of the Plan's Participation in a Loan at the time of closing and throughout the term of the Loan, and the Plan will have first priority to proceeds from disposition of the Collateral in the event of a default; and (e) all of the terms and conditions of the Participations will be at least as favorable to the Plan as those available

to the Plan in an arm's-length transaction with an unrelated party.

14. In summary, the Trustee represents that the proposed transactions meet the statutory criteria of section 408(a) because: (a) The Plan's purchase of a Participation will be reviewed and approved by the Trustee; (b) the Plan's Participation will be secured by Collateral worth at least 200% of the value of the Participation; (c) the Participations will be limited to a 5 year period; and (d) the Trustee has determined that the Participations are in the interests of and protective of the Plan and its participants and beneficiaries.

For Further Information Contact: Mr. David Lurie of the Department, telephone (202) 523-8884. (This is not a toll-free number.)

Profit-Sharing Plan & Trust Agreement of John V. Krippaehne, D.M.D., P.C. (the P/S Plan) Money-Purchase Pension Plan & Trust Agreement of John V. Krippaehne, D.M.D., P.C. (the M/P Plan) Located in Portland, Oregon

[Application Nos. D-5912 and D-5913]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted the restrictions of section 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to proposed lease, effective January 1, 1985, of certain real property by the above named plans (collectively, the Plans) to Dr. John V. Krippaehne (Dr. Krippaehne), a party in interest with respect to the Plans, provided that (a) the terms of the transaction are at least as favorable to the Plans as those the Plans could obtain in a similar transaction with an unrelated party, and (b) Form 5330 is filed and excise taxes are paid as stated in representation 5, below.

Effective Date: If the proposed exemption is granted, the exemption will be effective January 1, 1985.

Summary of Facts and Representations

1. Each of the Plans covered three participants as of June 29, 1984, including Dr. Krippaehne, who is also an officer, shareholder, and director of the employer (the Employer) of such participants. As of August 31, 1984, the

P/S Plan's assets totalled \$269,509 and the M/P Plan's assets totalled \$195,833.

2. On or before June 28, 1984, Pacific Western Bank Trust Group (the Bank), of Portland, Oregon, agreed to serve as an independent trustee with respect to the proposed transaction and began reviewing same. It is represented that the Bank is independent of Dr. Krippaehne and the Employer. The Bank has been in existence since 1969. Its Employee Benefits section administers approximately 1,000 accounts, with a total value of approximately \$250,000,000, and serves in various capacities, including trustee, custodian, investment advisor, and administrator. The Bank's Trust Real Estate Division is responsible for the collection of all note payments, mortgages, and contracts for those types of assets in the various accounts it maintains. This division is responsible for approximately \$30,000,000 in real estate assets and has extensive experience in lease negotiations. The trust officer heading the Bank's real estate section is, according to the Bank, completely conversant with the real estate market in the Portland area as this section is responsible for managing, purchasing, selling, and monitoring real estate held in various trust accounts by the Bank. The Bank believes it has developed, over the years, the necessary expertise in both real estate and the Act in order to fulfill its role as an independent fiduciary with regard to these types of transactions.

3. The P/S Plan owns a $\frac{1}{4}$ interest as tenant in common in a parcel of land (the Land), described below. The M/P Plan owns the remaining $\frac{3}{4}$ interest as tenant in common. The Land, known as Tall Trees Townhouses Land, comprises .91 acres located at 10750 N.E. Halsey Street, Portland, Oregon 97220, and is improved by a 17-unit apartment complex presently owned by Dr. Krippaehne. The Land is landscaped, treed, and because of its location off of Halsey Street, is located in a somewhat quiet neighborhood. The Land has good access from N.E. Halsey Street and is not far from access to two interstate freeway systems. The Light-Rail System being established in the Portland area will pass nearby, thus providing public transportation to and from the Portland area.

4. The Land was appraised by John E. Slocum, MAI, of Curtis, MacKenzie & Slocum, Inc., a licensed real-estate appraiser in the State of Oregon, who has worked as an appraiser since 1973 and is a member of the American Institute of Real Estate Appraisers. Mr. Slocum certifies that he has no present

or contemplated future interest in either the Land or the parties involved. Mr. Slocum has determined that as of July 23, 1984, the air market value of the Land was \$54,000 and the fair market rent of the Land was \$5,400 and the fair market rent of the Land was \$5,400 for the next annual period. His appraisal does not contain a representation as to whether or not a greater fair rental value should obtain because the Land is leased to Dr. Krippaehne, who owns both the improvements and the Employer, which sponsors the Plans, which own the Land.

5. The Plans acquired the Land on June 1, 1974, from Piper Investment Properties, Ltd., for \$24,000, \$18,000 of which was paid by the P/S Plan and the remaining \$6,000, by the M/P Plan. By agreement dated June 1, 1974 (the Original Lease), the Plans leased the Land to Dr. Krippaehne for an initial 10-year term, which expired May 31, 1984. The Original Lease permitted Dr. Krippaehne to remain on the Land after May 31, 1984 as a tenant from month to month, subject to all of the Original Lease provisions except those for termination. The applicant states that Dr. Krippaehne has consistently complied with the Original Lease from its inception to the present. The applicant represents that the Original Lease met the requirements of section 414(c)(2) of the Act because the transaction was entered into pursuant to a binding contract which was in effect prior to July 1, 1974, the Original Lease remained at least as favorable to the Plans as an arm's-length transaction with an unrelated party would have been, and the execution of the Original Lease agreement was not, at the time of execution, a prohibited transaction under the Code.⁴ Dr. Krippaehne has continued to use the Land after June 30, 1984. The applicant represents that if such use constitutes a prohibited transaction and is not granted exemptive relief, Form 5330, Return of Initial Excise Taxes Related to Pension and Profit-Sharing Plans, will be filed with the Internal Revenue Service and the excise taxes due will be paid within 60 days of the date the Department concludes its action on this exemption application.⁵

⁴Section 414(c)(2) of the Act provides an exemption until June 30, 1984, from the prohibited transaction provisions of the Act for leases meeting specified requirements. The Department is expressing no opinion herein as to whether the Original Lease is exempt under this section.

⁵The Department notes that Dr. Krippaehne's continued use of the Land after June 30, 1984, constitutes a prohibited transaction, within the meaning of sections 406 and 407 of the Act, which is not covered by this proposed exemption prior to

6. The Bank, as independent trustee for the Plans, and Dr. Krippaehne propose to enter into a new lease (the New Lease) regarding the Land effective January 1, 1985, if the proposed exemption is granted. The New Lease provides for an initial term of 9 years, may be renewed for successive 3-year terms if Dr. Krippaehne is not in default of any provision of the New Lease, and also permits Dr. Krippaehne to remain on the Land after the New Lease expires under a month-to-month tenancy (Holding Over) which the Bank may terminate at will at any time. The Bank represents that prior to executing any extension, renewal, or Holding Over, the Bank must first determine that exercising these provisions would be in the best interest of the Plans and their participants and beneficiaries. The rent required under the New Lease is \$450 per month initially and will be adjusted every 3 years during the initial term, any renewal period, and any Holding Over to equal the greater of: (a) The then current fair market rental value as determined by an independent appraiser who is a SRA or MAI member, or (b) the rent required for the immediately preceding period. If the proposed exemption is granted, the initial rent will be increased to equal the fair market rental value of the Land as of the effective date of the New Lease as determined by the Bank, taking into consideration Dr. Krippaehne's ownership of the improvements on the Land. The New Lease is a triple net lease in which the Plans are required to bear no expenses, or incur any cost during the duration of the New Lease. All costs and expenses, including liability insurance covering both the Plans and Dr. Krippaehne, are Dr. Krippaehne's responsibility. The New Lease specifies that the Plans have absolutely no responsibility for the property except not to place any liens or encumbrances on the Land.

7. The Bank, as independent trustee, has reviewed the terms and conditions of the New Lease, which was submitted to the Department by letter dated January 2, 1985. The Bank's review included a review of Mr. Slocum's appraisal and discussions with him concerning his appraisal as it relates to the real estate environment in the Portland area and to this particular investment by the Plans. The Bank states that its review was done prior to

January 1, 1985, the effective date of the New Lease (described in 6, below). As mentioned in footnote 1, above, the Department is expressing no opinion as to whether Dr. Krippaehne's use of the Land for any period prior to July 1, 1974, also constitutes a prohibited transaction.

and during the drafting of the New Lease. The Bank represents that based upon this review, as well as the Bank's experience in the real estate markets and its review of the Plans' assets, the Bank concludes that the proposed transaction is in the best interest of each of the Plans and their participants and beneficiaries. The Bank also states that it feels the New Lease is as good and as fair a lease as any to which two independent parties would agree. The Bank feels the New Lease reflects the market conditions in the Portland Metropolitan area and should not be considered as being favored because the owner of the apartment complex (i.e., Dr. Krippaehne, the tenant) is in a position to control the owner of the Land to be leased (i.e., the Plans).

8. In reaching the conclusions stated in 7, above, the Bank found that: (a) There are very few, if any, liquidity requirements of the Plans, and 51% of the Plans' combined assets are in liquid investments which could be used if the Plans needed to raise funds; (b) all costs and expenses under the Proposed Lease are Dr. Krippaehne's responsibility; and (c) regarding diversification, the Plans' combined assets are 17% in real estate, 15% in stocks, 14% in bonds, and 37% in money market instruments and certificates of deposit, and the balance in receivables. The Bank states that as the independent trustee for the Plans, the Bank will receive all payments under the New Lease, will insure proper payment of taxes and insurance, will periodically inspect the Land, will act in good faith at all times in the best interest of the Plans and their participants, will have all the authority necessary to insist upon fairness of terms for the Plans, and will not show any type of favoritism toward Dr. Krippaehne because he is the owner of the apartment complex and is in a position to control the Plans, which own the Land.

9. In summary, the applicant represents that the proposed transaction satisfies the exemption criteria set forth in section 408(a) of the Act because: (a) The initial rent under the New Lease will be no less than the fair market rental value of the Land as of the effective date of the New Lease; (b) the rent will be increased every 3 years to equal the then current fair market rental value of the Land, as determined by a qualified independent appraiser, if such value exceeds the rent payable during the immediately preceding period; (c) the Plans will not be responsible for any costs or expenses under the New Lease; (d) an independent fiduciary, the Bank, has reviewed the Plans' assets and the

terms and conditions of the New Lease prior to and during its drafting and has determined that the proposed transaction is in the best interest of the Plans and their participants and beneficiaries; and (e) the Bank will be the lessor, on behalf of the Plans, under the New Lease and represents that it will act in good faith and in the best interests of the Plans and their participants in enforcing and exercising the provisions of the New Lease.

For further information contact: Mrs. Miriam Freund, of the Department, telephone (202) 523-8971. (This is not a toll-free number.)

Raleigh Medical Group, P.A. Profit Sharing Plan (the Plan) Located in Raleigh, North Carolina

[Application No. D-5935]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 16471, April 28, 1975). If the exemption is granted the restrictions of section 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to the proposed sale by the Plan of a parcel of unimproved real property (the Property) to BEDB Realty Associates (the Partnership), a partnership which is a party in interest with respect to the Plan, provided that the price received is no less than the fair market value of the Property on the date of sale.

Summary of Facts and Representations

1. The Plan is a defined contribution pension plan with sixteen participants and total assets of \$566,127.83 as of April 30, 1984. The Plan is sponsored by the Raleigh Medical Group, P.A. (the Employer), a North Carolina professional corporation engaged in a multi-specialty medical practice in Raleigh, North Carolina. The trustees of the Plan (the Trustees) are three shareholders and employees of the Employer. The Partnership is comprised of the four sole shareholders of the Employer, three of whom are the Trustees.

2. The Property is Lot #13 in the North Hills Office Center on Six Forks Road in Raleigh, North Carolina. The Plan purchased the Property on April 26, 1983 from Central Carolina Realty, Inc., an unrelated party, for a purchase price of \$210,000, consisting of a cash down payment of \$105,000 and a sixty-day, no-

interest promissory note of \$105,000, which has been paid. The Plan also paid closing costs of \$867.50 and as of December 18, 1984 had paid \$3,470.20 in taxes and carrying expenses on the Property. As of April 30, 1984, the Property had a fair market value of \$6.00 per square foot, according to Algie Stephens (Stephens), a real estate broker with the firm of Central Carolina Realty, Inc. in Raleigh, North Carolina. The Property consists of 61,482 square feet. According to an appraisal performed on February 21, 1985 by Worthy & Wachtel and Associates (WSA), a commercial real estate firm in Raleigh, North Carolina, the fair market value of the Property as of that date was \$5.00 per square foot. As of April 30, 1984, the most recent year end for the Plan, the Property constituted approximately 65 percent of the total assets of the Plan and the Trustees have determined that it creates a liquidity problem for the Plan. The Plan currently receives no income from the Property. Although the Property has appreciated substantially since its acquisition by the Plan, the Trustees have determined that further appreciation of the Property is unlikely due to recent rapid development in the surrounding area resulting in a saturation of office space. The Trustees have determined that the Plan should divest itself of the Property at this time in order to realize the Property's recent appreciation and to enable the Plan to diversify its assets and relieve a liquidity problem.

3. The Partnership is currently in need of a parcel of unimproved real property to develop in pursuit of its partner's objective, which is the commercial development of real property and the lease of such developed property to the Employer. The Trustees are requesting an exemption to permit the Partnership to purchase the Property from the Plan under the circumstances described herein. According to the terms proposed by the Partnership, if the exemption is granted the Partnership will pay the Plan cash for the Property in an amount no less than the Property's fair market value and will pay all fees and closing costs related to the sale, including recent appraisal fees. While the Property's fair market value was rounded to \$310,000 as of February 21, 1985, according to WSA's appraisal, since April 31, 1984, the Property has been valued as a Plan asset at \$368,892, based on Stephens' appraisal of \$6.00 per square foot as of April 30, 1984. The purchase price to be paid by the Partnership will be the higher figure of \$368,892.

4. The Trustees have appointed the United Carolina Bank (the Bank) of

Raleigh, North Carolina, to act as an independent fiduciary on behalf of the Plan with respect to the proposed sale by making an independent determination as to whether such proposed transaction will be in the best interests and protective of the participants and beneficiaries of the Plan. The Bank represents that it is independent of and unrelated to the Partnership and the Employer. After a review and analysis of all proposed terms of the Plan's proposed sale of the Property to the Partnership, the Bank represents that such transaction will be in the best interests of the participants and beneficiaries of the Plan. The Bank notes that the sale will be a one-time transaction for cash in an amount which is no less than the fair market value of the Property. The Bank finds that the proposed transaction will advantage the Plan by divesting it of a non-income producing asset which constitutes a high percentage of Plan assets and presents a liquidity problem. In recommending that the Plan proceed with the proposed sale, the Bank also notes that all costs associated with the sale will be borne by the Partnership. If the required exemption is granted, the Bank will remain as the Plan's independent fiduciary with respect to the Property through the closing of the sale transaction under the terms described herein.

5. In summary, the applicants represent that the proposed transaction satisfies the criteria of section 408(a) of the Act for the following reasons: (1) The interests of the Plan with respect to the proposed transaction are and will be represented by a fiduciary, the Bank, which is independent of the Partnership and the Employer; (2) after a review and analysis of the proposed transaction, the Bank has determined that it will be in the best interests of the participants and beneficiaries of the Plan; (3) the proposed transaction will enable the Plan to divest of an asset which produces no income for the Plan; (4) the proposed sale will be a one-time transaction for cash; (5) the proposed sale will enable the Plan to address a liquidity problem, as the Property constitutes approximately 65 percent of the assets of the Plan; (6) the Plan will receive a purchase price for the Property which is no less than the Property's fair market value; and (7) the Partnership will pay all costs associated with the sale transaction.

For Further Information Contact: Ronald Willett of the Department, telephone (202) 523-8194. (This is not a toll-free number.)

Dow Chemical Company Voluntary Group Accident Plan (the Plan) Located in Midland, Michigan

[Application No. D-6057]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted, the restrictions of section 408 (a) and (b) of the Act shall not apply, effective October 1, 1984, to the reinsurance of risks and the receipt of premiums therefrom by Dorinco Reinsurance Company (Dorinco) from the insurance contracts sold by American Home Assurance Company (American) to provide benefits to employees of Dorinco and the Dow Chemical Company (Dow) under the Plan, provided the following conditions are met:

(a) Dorinco—

(1) Is a party in interest with respect to the Plan by reason of a stock or partnership affiliation with Dow that is described in section 3(14) (E) or (G) of the Act.

(2) Is licensed to sell insurance in at least one of the United States or in the District of Columbia.

(3) Has obtained a Certificate of Compliance from the Department of Insurance of its domiciliary state, Michigan, which has neither been revoked nor suspended; and

(4)(A) Has undergone an examination by an independent certified public accountant for its last completed taxable year immediately prior to the taxable year of the reinsurance transaction; or

(B) Has undergone a financial examination (within the meaning of the law of its domiciliary state, Michigan) by the Michigan Department of Insurance within 5 years prior to the end of the year preceding the year in which the reinsurance transaction occurred.

(b) The Plan pays no more than adequate consideration for the insurance contracts;

(c) No commissions are paid with respect to the direct sale of the contract, or the reinsurance thereof; and

(d) For each taxable year of Dorinco, the gross premiums and annuity considerations received in that taxable year by Dorinco for life and health insurance or annuity contracts for all employee benefit plans (and their employers) with respect to which Dorinco is a party in interest by reason of a relationship to such employer

described in section 3(14) (E) or (G) of the Act does not exceed 50 percent of the gross premiums and annuity considerations received for all lines of insurance (whether direct insurance or reinsurance) in that taxable year by Dorinco. For purposes of this condition (d):

(1) The term "gross premiums and annuity considerations received" means as to the numerator the total of premiums and annuity considerations received, both for the subject reinsurance transactions as well as for any direct sale or other reinsurance of life insurance, health insurance or annuity contracts to such plans (and their employers) by Dorinco. This total is to be reduced (in both the numerator and denominator of the fraction) by experience refunds paid or credited in that taxable year by Dorinco.

(2) All premium and annuity considerations written by Dorinco for plans which it alone maintains are to be excluded from both the numerator and denominator of the fraction.

Effective Date: If granted, this proposed exemption will be effective October 1, 1984.

Preamble

On August 7, 1979, the Department published a class exemption [Prohibited Transaction Exemption 79-41 (PTE 79-41), 44 FR 46365] which permits insurance companies that have substantial stock or partnership affiliations with employers establishing or maintaining employee benefit plans to make direct sales of life insurance, health insurance or annuity contracts which fund such plans, if certain conditions are satisfied.

In PTE 79-41, the Department stated its view that if a plan purchases an insurance contract from a company that is unrelated to the employer pursuant to an arrangement or understanding, written or oral, under which it is expected that the unrelated company will subsequently reinsure all or part of the risk related to such insurance with an insurance company which is a party in interest with respect to the plan, the purchase of the insurance contract would be a prohibited transaction.

The Department further stated that as of the date of publication of PTE 79-41, it had received applications for exemption under which a plan or its employer would contract with an unrelated company for insurance, and that unrelated company would, pursuant to an arrangement or understanding, reinsure part or all of the risk with (and cede part or all of the premiums to) an insurance company affiliated with the

employer maintaining the plan. The Department felt that it would not be appropriate to cover the various types of reinsurance transactions for which it had received applications within the scope of the class exemption, but would instead consider such applications on the merits of each individual case.

Summary of Facts and Representations

1. Dow is a large, publicly-held corporation organized under the law of the State of Delaware. The dominant portion of Dow's business consists of the manufacture and sale of chemicals, metals, plastic materials and products, and pharmaceutical, agricultural and consumer products.

2. Dorinco, a wholly-owned subsidiary of Dow, is a licensed insurer and reinsurer incorporated in 1977 under the laws of the State of Michigan. Dorinco actively solicits reinsurance business in the state in which it is licensed. Dorinco is currently qualified to do business in 38 states and the District of Columbia. At the end of 1983, Dorinco had capital paid up of \$10 million and surplus of \$43,936,000. During 1983, Dorinco collected \$63,986,000 in total gross premiums.

3. The Plan is a welfare benefit plan providing death and disability benefits upon the accidental death or disability of Dow employees. As of September 24, 1984, there were approximately 43,000 covered participants under the Plan.

4. Dow has provided benefits under the Plan through insurance contracts sold by American since 1965. American is a stock insurance company owned by its shareholders and it is not related to Dow or Dorinco. On October 1, 1984, American entered into a reinsurance contract with Dorinco with respect to risks American insures. The Plan is not a party to this agreement. By its terms, the agreement provides that American will pay Dorinco 50 percent of the premiums it receives in exchange for which Dorinco has agreed to insure American for 50 percent of the risk. The anticipated amount of the premium which is reinsured by Dorinco is less than \$1 million and it does not exceed 5 percent of the total net premiums received by Dorinco for the year 1983 (\$55,926,239). According to the exemption application, American's liability for all of the benefits promised under its contract will not be affected by the reinsurance contract.

5. The applicant represents that the subject reinsurance transactions meet all of the conditions of PTE 79-41 covering direct insurance transactions:

(a) Dorinco is a party in interest with

respect to the Plan as described in section 3(14)(G) of the Act by reason of its stock affiliation with Dow.

(b) Dorinco is licensed to sell insurance in at least one of the United States.

(c) Dorinco obtained a Certificate of Compliance, which has never been revoked or suspended, from the Department of Insurance of the State of Michigan, on March 18, 1977. Such authorization is automatically renewed each year and continues to be effective unless rescinded.

(d) Dorinco has undergone a financial examination by the Department of Insurance of the State of Michigan as of June 30, 1982, and expects to undergo such financial examinations every three years in the future. During the course of future examinations, it is anticipated that the proposed reinsurance contracts with American will also be examined.

(e) Dorinco has undergone in the past, and will continue to undergo in the future, an annual examination by an independent certified public accounting firm.

(f) The Plan pays no more than adequate consideration for the insurance contracts. Moreover, the proposed reinsurance contracts will not in any way affect premium costs.

(g) After October 1, 1984, no commissions will be paid with respect to either the insurance contracts with American or the reinsurance contract between American and Dorinco.

(h) The gross premiums received by Dorinco during any taxable year from the reinsurance transactions, when considered along with any other premiums or annuity considerations received by Dorinco from employee benefit plans (and their employers) with respect to which Dorinco is a party in interest by reason of a 50 percent or more ownership affiliation, will not exceed 50 percent of the total premiums and annuity considerations received by Dorinco during such taxable years.

8. In summary, the applicant represents that the subject transactions meet the criteria of section 408(a) of the Act because: (a) The insurance could not be purchased directly from Dorinco more economically than it is purchased from American; (b) participants and beneficiaries of the Plan are afforded insurance protection by American, a large insurer in the United States, at competitive rates arrived at through arm's length negotiations; (c) Dorinco is a sound, viable insurance company which has been in business for many years, and which does a substantial amount of business outside its affiliated

group of companies; and (d) each of the protections provided to the Plan by PTE 79-41 will be met under the subject reinsurance transactions.

For further information contact: Ms. Jan D. Broady of the Department, telephone (202) 523-8971. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under section 408(a) of the Act and/or section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries and protective of the rights of participants and beneficiaries of the plan; and

(3) The proposed exemptions, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

(4) The proposed exemptions, if granted, will be subject to the express condition that the material facts and representations contained in each application are true and complete, and that each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, D.C., this 11th day of April 1985.

Elliot I. Daniel,

Acting Assistant Administrator for Regulations and Interpretations, Office of Pension and Welfare Benefit Programs, U.S. Department of Labor.

[FR Doc. 85-9192 Filed 4-16-85; 8:45 am]

BILLING CODE 4510-29-M

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Astronomical Sciences; Meeting

In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, as amended, the National Science Foundation announces the following meeting:

Name: Advisory Committee for Astronomical Sciences.

Date and Time: May 6, 9 am-5 pm and 7:30 pm-10:00 pm; May 7, 9 am-5 pm.

Place: Open Sessions: Main Conference Room, Kitt Peak National Observatory Headquarters, Tucson, AZ; Closed Sessions: Holiday Inn-Broadway, 180 W. Broadway, Tucson, AZ.

Type of Meeting: Partially Closed—May 6, 7:30-10:00 pm.

Contact Person: Dr. Laura P. Bautz, Director, Division of Astronomical Sciences, Room 615, National Science Foundation, Washington, DC 20550 202 357-9488.

Summary Minutes: May be obtained from the contact person at the above address.

Purpose of Committee: To provide and recommendations concerning research programs, proposals, and projects in NSF-funded astronomy with the objective of achieving the highest quality forefront research for the funds allocated. To provide advice and recommendations concerning short range and long range plans in astronomy, including a recommendation of relative priorities.

Agenda:

Monday, May 6

9 am-5 pm Open Session: Status of Selected Items in NSF's FY 1986 Budget, Proposed Program Changes at the National Optical Astronomy Observatories, Needs and Priorities for FY 1987 Outlook.

7:30 pm-10:30 pm Closed: Closed Session for Discussion of Selected Proposals under Review.

Tuesday, May 7

9 am-5 pm Open Session: Continuation of Discussions from Previous Day, Future Large Optical/Infrared Telescopes.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with proposals. These matters are within exemptions (4) and (6) of 5 U.S.C. 552b(c). Government in the Sunshine Act.

Authority to Close Meeting: This determination was made by the Committee Management Officer pursuant to provisions of section 10(d) of Pub. L. 92-463. The Committee Management Officer was delegated the authority to make such determinations by the Director, NSF, July 6, 1979.

M. Rebecca Winkler,
Committee Management Officer.

April 12, 1985.

[FR Doc. 85-9257 Filed 4-16-85; 8:45 am]

BILLING CODE 7555-01-M

Advisory Committee for Physics; Meeting

In accordance with the Federal Advisory Committee Act Pub. L. 92-463, the National Science Foundation announces the following meeting:

Name: Advisory Committee for Physics.

Date and Time: May 9, 1985: 10:00 a.m.-6:00 p.m. (Open); May 10, 1985: 8:30 a.m.-Noon (Open); 1:00 p.m.-2:30 p.m. (Closed); 2:30 p.m.-5:00 p.m. (Open).

Place: National Science Foundation, 1800 G Street NW., Washington, D.C. 20550, room 540 each day.

Type of meeting: Part Open.

Contact Person: Dr. Marcel Bardon, Director, Division of Physics, National Science Foundation, Washington, D.C. 20550. Telephone (202) 357-7985.

Summary of Minutes: May be obtained from Mrs. Phyllis Hurley, Division of Physics, National Science Foundation, Washington, D.C. 20550.

Purpose of Committee: To provide advice and recommendations concerning support for research in physics.

Agenda: May 9, 1985, 10:00 a.m.-6:00 p.m. (Open). Oversight review of NSF support of atomic, molecular, and plasma physics, including presentations by NSF staff and the report of the Subcommittee for Review of the NSF Atomic, Molecular, and Plasma Physics Program.

May 10, 1985, 8:30 a.m.-Noon; 2:30 p.m.-5:00 p.m. (Open). Continuation of previous day's discussions.

May 10, 1985, 1:00 p.m.-2:30 p.m. (Closed). Review of proposals for FY 1987 budget planning.

Reason for Closing: The proposals being discussed include information of a proprietary or confidential nature including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These discussions are within exemptions (4) and (6) of 5 U.S.C. 552b(c), Government in the Sunshine Act.

Authority to Close Meeting: This determination was made by the Committee Management Officer pursuant to provisions of section 10(d) of Pub. L. 92-463. The Committee Management Officer was delegated the authority to make such

determinations by the Director, NSF, on July 6, 1979.

M. Rebecca Winkler,
Committee Management Officer.

[FR Doc. 85-9256 Filed 4-16-85; 8:45 am]

BILLING CODE 7555-01-M

Advisory Panel for Law and Social Sciences; Meeting

In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, as amended the National Science Foundation announces the following meeting:

Name: Advisory Panel for Law and Social Sciences.

Date/Time: May 10th and 11th, 1985; 9:00 a.m. to 6:00 p.m.

Place: Room 1242-B, National Science Foundation, 1800 G Street, NW., Washington, D.C. 20550.

Type of Meeting: Closed.

Contact Person: Dr. Felice J. Levine, Program Director, Law and Social Sciences Program, Room 312, National Science Foundation, 1800 G Street, NW., Washington, D.C. 20550; telephone 202/357-9567.

Purpose of Panel: To provide advice and recommendation concerning support for research in Law and Social Sciences.

Agenda: To review and evaluate research proposals and projects as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are within exemptions (4) and (6) of 5 U.S.C. 552b(c), Government in the Sunshine Act.

Authority to Close Meeting: This determination was made by the Committee Management Officer pursuant to provisions of section 10(c) of Pub. L. 92-463. The Committee Management Officer was delegated the authority to make such determinations by the Director, NSF, on July 6, 1979.

M. Rebecca Winkler,
Committee Management Officer.

April 12, 1985.

[FR Doc. 85-9261 Filed 4-16-85; 8:45 am]

BILLING CODE 7555-01-M

Advisory Panel for Regulatory Biology; Meeting

In accordance with the Federal Advisory Committee Act, as amended, Pub. L. 92-463 the National Science Foundation announces the following meeting:

Name: Advisory Panel for Regulatory Biology.

Date and Time: May 8, 9, and 10, 1985 8:30 a.m. to 5:00 p.m. each day.

Place: May 8, 1985, room 523, 8:30 a.m. to 12:00 p.m.; room 421, 12:00 p.m. to 5:00 p.m.; May 9 and 10, 1985 Room 421.

Type of Meeting: Closed.

Contact Person: Dr. Lewis Greenwald, Program Director, Regulatory Biology Program, Room 332, National Science Foundation Washington, DC 20550 Telephone 202/357-7975.

Purpose of Advisory Panel: To provide advice and recommendations concerning support for research in regulatory biology.

Agenda: To review and evaluate research proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are within exemptions (4) and (6) of 5 U.S.C. 552b(c), Government in the Sunshine Act.

Authority To Close Meeting: This determination was made by the Committee Management Officer pursuant to provisions of section 10 (d) of Pub. L. 92-463. The Committee Management Officer was delegated the authority to make such determinations by the Director, NSF, on July 6, 1979.

April 12, 1985.

M. Rebecca Winkler,
Committee Management Officer.

[FR Doc. 85-9259 Filed 4-16-85; 8:45 am]

BILLING CODE 7555-01-M

Advisory Panel for Sociology; Meeting

In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, the National Science Foundation announces the following meeting:

Name: Advisory Panel for Sociology.

Date and Time: May 6-7, 1985—Monday—9:00 am to 5:30 pm; Tuesday—9:00 am 4:00 pm.

Place: National Science Foundation, 1800 G Street NW., Washington, DC, Room 523.

Type of Meeting: Closed.

Contact Person: Joanne Miller, Program Director for Sociology or Thomas M. Guterbock, Associate Program Director for Sociology, Room 316, National Science Foundation, Washington, DC 20550 Telephone: (202) 357-7802.

Purpose of Subpanel: To provide advice and recommendation concerning support for research in the Sociology Program.

Agenda: To review and evaluate research proposals and projects as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are within exemptions (4) and (6) of 5 U.S.C. 552b (c), Government in the Sunshine Act.

Authority To Close Meeting: This determination was made by the Committee Management Officer pursuant to provisions of section 10(d) of Pub. L. 92-463. The Committee Management Officer was delegated the authority to make such determinations by the Director, NSF, of July 6, 1979.

April 12, 1985.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 85-9258 Filed 4-16-85; 8:45 am]

BILLING CODE 7555-01-M

Committee on Equal Opportunities in Science and Technology and of its Subcommittees; Meeting

In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, the National Science Foundation announces the following meetings:

Names/Dates/Times/Places:

Full Committee—May 9, 9:00-12:00 Noon, Room 543.

Subcommittee on Women—May 9, 1:30-5:00 p.m., Room 543.

Subcommittee on Minorities—May 9, 1:30-5:00 p.m., Room 1242B.

Full Committee—May 10, 9:00-12:00 Noon, Room 543.

Subcommittee on Disabled Scientists—May 10, 1:30-3:30 p.m., Room 543—National Science Foundation, 1800 G Street NW., Washington, D.C. 20550.

Type of Meeting: Open.

Contact Person: Ms. Jane Stutsman, Executive Secretary of the Committee, National Science Foundation, Rm. 425, 1800 G Street NW., Washington, D.C. 20550, Telephone: 202/357-9418.

Purpose of Subcommittees: Responsible for all Committee matters relating to the participation in and opportunities for education, training, and research for minorities, women and handicapped persons in science and technology, and the impact of science and technology on them.

Summary Minutes: May be obtained from the contact person at the above stated address.

Agenda: The Subcommittees will consider mechanisms to increase participation of minorities, women and handicapped persons in Foundation programs, research projects, and on all NSF advisory committees. They will also advise the Director on how to modify NSF policies and procedures relating to minority, women and handicapped persons as well as the internal distribution of funds to implement this program.

M. Rebecca Winkler,

Committee Management Officer.

April 12, 1985.

[FR Doc. 85-9260 Filed 4-16-85; 8:45 am]

BILLING CODE 7555-01-M

PACIFIC NORTHWEST ELECTRIC POWER AND CONSERVATION PLANNING COUNCIL

Options Evaluation Task Force; Regular Meeting

AGENCY: Options Evaluation Task Force of the Pacific Northwest Electric Power and Conservation Planning Council (Northwest Power Planning Council).

ACTION: Notice of meeting to be held pursuant to the Federal Advisory Committee Act, 5 U.S.C. Appendix I, 1-4. Activities will include:

- Update on Council's Decision Analysis Model.
- Discussion of Load/Conservation Uncertainty Treatment.

Status: Open.

SUMMARY: The Northwest Power Planning Council hereby announces a forthcoming meeting of its Options Evaluation Task Force.

DATE: Monday, April 29, 1985, 9:30 a.m.

ADDRESS: The meeting will be held at the Council Central Office at 850 SW. Broadway, Suite 1100, in Portland, Oregon.

FOR FURTHER INFORMATION CONTACT: Wally Gibson, (503) 222-5161.

Edward Sheets,

Executive Director.

[FR Doc. 85-9198 Filed 4-16-85; 8:45 am]

BILLING CODE 0000-00-M

OFFICE OF PERSONNEL MANAGEMENT

Privacy Act of 1974; Publication of a Proposed New System of Records and an Amendment of an Existing System

AGENCY: Office of Personnel Management.

ACTION: Notice; Publication of a proposed new system of records and an amendment of an existing system.

SUMMARY: This notice propose the establishment of OPM/Govt-10, Employees Medical File System Records, which is a new Government-wide system of records for Federal employee medical records retained by agencies on active civilian employees and in Federal Records Storage Centers for inactive employees. Because some of the records to be included in this new system are now included in OPM-GOVT-1, General Personnel Records, system, necessary amendments to that system's notice are also being proposed. Elsewhere in this issue are proposed rules pertaining to the records in the new system.

DATE: Comments must be received on or before May 17, 1985. The notice, including the routine uses, becomes effective on June 17, 1985 without further notice, unless comments necessitate otherwise.

ADDRESS: Send or deliver written comments to the Assistant Director for Workforce Information, Office of Personnel Management, Room 5415, 1900 E Street, NW, Washington, D.C. 20415.

FOR FURTHER INFORMATION CONTACT: William H. Lynch, Workforce Records Management Division, (202) 632-5433.

SUPPLEMENTARY INFORMATION: The Office of Personnel Management (hereafter referred to as "the Office") is proposing to establish a new Privacy Act System of records to cover employees medical records (manual, automated, microfilm, or microfiche) maintained by agencies including employee on-the-job exposure and injury records (1) at the work site; (2) in agency dispensary, medical, health, or safety offices; and (3) in servicing personnel or other designated offices. Records included in this system are those created during the application for Federal employment process (when the individual is subsequently hired) and during the employee's career. These records are retained to ensure protection of employees' health and safety, as well as governmental interests, and to meet requirements of the Office, the Occupational Safety and Health Administration (OSHA), and the Office of Workers' Compensation Programs (OWCP).

This system does not include (1) patient records; i.e., those normally associated with treatment of individuals admitted to or who voluntarily seek treatment at health care facility concerning matters not pertaining to a condition of employment or arising as a result of an on-the-job occurrence; (2) records created as a result of epidemiological research studies; or (3) case files; i.e., the files maintained by the Office (medical disqualification decisions and disability retirement files), OSHA (relating to unsafe/unhealthy work conditions), and the OWCP compensation claim files). However, in some instances these case files will contain medical records that are included in this system, and it is possible that the proposed system would continue to retain copies of them after the creation of such case files. Efforts will be made to ultimately prevent unnecessary duplication of records. In order to ensure Privacy Act coverage on a transition basis, these types of records

are described as being part of the proposed system.

This proposal results from the recommendations made by an Interagency Task Group on Federal Employee Medical Records, February 1981. The Task Group was co-chaired by the Office and OSHA and was established to review what was widely agreed by agencies and employee representatives to be a widespread problem (i.e., the lack of consistent, Government-wide medical records management policy) and to make recommendations for the problem's solution. After 18 months of examination, including advice from agencies, labor organizations, and other interested public and private sector medical practitioners and records managers, the Task Group recommended that (1) agencies establish an Employee Medical Folder (EMF) as a permanent repository for the medical records of a Federal civilian employee; (2) the Office establish policies and regulations governing the control and disposition of such records, including guidance on access to and release of medical information; and (3) medical records accompany an active employee as he or she moves within an agency or to another agency and be stored along with his or her Official Personnel Folder (OPF) when no longer employed. With the concurrence and active participation of OSHA, OWCP, and the National Archives and Records Administration (NARA) as the Government's records manager, the Office's Director approved the establishment of the Employee Medical Records File System (EMFS) which includes an EMF.

It is essential that regularization of medical records management provide for the retention of records vital to the employee's and the Government's interests on a long-term basis, and provide protection of personal privacy and compliance with the Privacy Act. Additionally, agencies and interested parties must be provided with adequate guidance on how and when such sensitive personal records may be disclosed both to officials of the custodial agency as well as to others outside that agency.

Therefore, consistent with the Office's long-standing Privacy Act policy as approved by the Office of Management and Budget regarding the inclusion of those employee personnel records that are under the Office's direct management or necessary to enable the Office to exercise its legal oversight responsibilities, the Office proposes to establish this new system of records. This action, along with the issuance of

minimally necessary regulations and Federal Personnel Manual guidance, will accomplish the Task Group's recommendations and will greatly improve medical records management and protection of personal privacy.

The Office believes that agency, employees, and other interested parties will be better served and agency costs will be reduced by placing such records in a separate system of records because such a system (1) establishes minimum essential uniformity and standards in medical recordkeeping; (2) facilitates accuracy in the description of records to be maintained; (3) more clearly defines the purposes for which the records are retained; (4) ensures that records are disclosed within the custodial agency and under routine uses only for purposes for which they are maintained; and (5) specifically identifies records appropriate for long-term retention, thus enabling compliance with OSHA recordkeeping standards; and (6) provides a reduction in the volume of medical records now being unnecessarily retained. This notice also modifies the existing notice for OPM/GOVT-1, General Personnel Records, to remove from that system those medical records to be retained in the new system. These actions are considered subject to the provisions of the Privacy Act (5 U.S.C. 552a(o)) requiring advance notice to Congress and the Office of Management and Budget. A "Report on New Systems" has been filed, concurrent with this publication, with Congress and the Office of Management and Budget. Because the records will remain covered by either OPM/GOVT-1 or an agency-specific system during the advance notice period, no waiver of this 60-day period has been requested.

Office of Personnel Management.

Donald J. Devine,

Director.

Accordingly, the Office gives notice of changes to the OPM/GOVT-1, General Personnel Records' system and proposes a new system to be identified as the OPM/GOVT-10, Employee Medical File System Records, as follows:

OPM/GOVT-1

SYSTEM NAME:

General Personnel Records.

* * * * *

CATEGORIES OF RECORDS IN THE SYSTEM:

All categories of records may include identifying information such as name(s), date of birth, home residence, mailing address, social security number, and home telephone. This system includes contents of the OPF as specified in

Federal Personnel Manual Supplement 293-31. Records in this system are:

a. Records reflecting work experience, educational level achieved, and specialized education or training occurring outside of Federal service.

b. Records reflecting Federal service and documenting work experience and specialized education or training received while employed. Such records contain information about past and present positions held; grades; salaries; duty station locations; and notices of all personnel actions such as appointments, transfers, reassignments, details, promotions, demotions, reductions-in-force, resignations, separations, suspensions, the Office of Personnel Management (hereafter referred to as "the Office") approval of disability retirement applications, retirement, and removals.

c. Records on enrollment or declination of enrollment in the Federal Employees Group Life Insurance Program and Federal Employee Health Benefit programs, as well as forms showing designation of beneficiary.

d. Records relating to an Intergovernmental Personnel Act assignment or Federal-private sector exchange program.

Note.—Some of these records may also become part of the OPM/CENTRAL-7, Intergovernmental Personnel Act Assignment Records system.

e. Records relating to participation in an agency federal executive or Senior Executive Service (SES) Candidate Development Program.

Note.—Some of these records may also become part of the OPM/CENTRAL-3, Federal Executive Development Records; or OPM/CENTRAL-13, Senior Executive Service Records systems.

f. Records relating to Government-sponsored training or participation in an agency's upward mobility program or other personnel programs designed to broaden an employee's work experiences and for purposes of advancement (e.g., an administrative intern program).

g. Records contained in the Central Personnel Data File (CPDF) maintained by the Office and exact substantive representations thereof in agency manual or automated personnel information systems. These data elements include many of the above records along with handicap and race/national origin codes. A definitive list of CPDF data elements is contained in Federal Personnel Manual Supplement 292-1, Personnel Data Standards.

h. Records on the SES, maintained by agencies for use in making decisions

affecting incumbents of these positions (e.g., relating to sabbatical leave programs, training, reassignments, and details) that are perhaps unique to the SES and which may be filed in the employee's OPF. These records may also serve as the basis for reports submitted to the Office's Workforce Effectiveness and Development Group for implementing the Office's oversight responsibilities concerning the SES.

i. Records concerning an employee's activities on behalf of the labor organization representing agency employees, including accounting of official time spent and documentation in support of per diem and travel expenses.

Note.—Alternatively, such records may be retained by an agency payroll office and thus subject to the agency's internal Privacy Act system for payroll records. The OPM/GOVT-1 system does not cover general agency payroll records.

j. To the extent that the records listed here are also maintained in an agency automated personnel or microform records system, those versions of the records are considered to be covered by this system notice. Any additional copies of these records (excluding performance appraisal and conduct-related documents maintained by first line supervisors and managers covered by the OPM/GOVT-2 system) maintained by agencies at field or administrative offices remote from where the original records exist are considered part of this system.

Note.—It is not the intent of the Office to limit this system of records only to those physically within the OPF. Records may be filed in other folders located in the offices other than where the OPF is located. Further, as indicated in the records location section, some of these records may be duplicated for maintenance at a site closer to where the employee works (e.g., in an administrative office or supervisor's work folder) and still be covered by this system.

OPM/GOVT-10

SYSTEM NAME:

Employee Medical File System Records.

SYSTEM LOCATION:

a. For current employees, records are located in agency medical, personnel, dispensary, health, safety, or other designated offices within the agency.

b. For former employees, most records will be located in an Employee Medical Folder (EMF) stored in Federal Records Storage Centers operated by the National Archives and Records Administration (NARA). In some cases, agencies may retain for a limited time (e.g., up to 1 year) some records on former employees.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former Federal civilian employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records maintained in this system include:

a. Medical records, forms, and reports completed or obtained when an individual applies for a Federal job and is subsequently employed;

b. Medical records, forms, and reports completed during employment as a condition of employment, either by the employing agency or by another agency, State or local government entity, or a private sector entity under contract to the employing agency;

Note.—Records maintained by an agency dispensary are included in the system only when they are the result of a condition of employment or related to an on-the-job occurrence.

c. Reports of on-the-job injuries and medical records, forms, and reports generated as a result of the filing of a claim for Workers' Compensation, whether the claim is accepted or not. (The official compensation claim file is not covered by this system; rather, it is part of the Department of Labor's Office of Workers' Compensation Program (OWCP) system of records.)

d. All other medical records, forms, and reports created on an employee during his/her period of employment, including any, retained on a temporary basis (e.g., those designated to be retained only during the period of service with a given agency) and those designated for long-term retention (i.e., those retained for the entire duration of Federal service and for some period of time after).

Note.—Records pertaining to employee drug or alcohol abuse counseling or treatment, and those pertaining to other employee counseling programs conducted under Health Service Programs established pursuant to 5 U.S.C. Chapter 79, are not part of this system of records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Executive Orders 12107 and 12196 and 5 U.S.C. Chapter 11, 31, 33, 43, 61, 63, and 83.

PURPOSE:

Records in this system of records are maintained for a variety of purposes, which include the following:

a. To ensure that records required to be retained on a long-term basis in order to meet the mandates of law, Executive order, or regulations (e.g., the Department of Labor's Occupational Safety and Health Administration

(OSHA) and OWCP regulations), are so maintained.

b. To provide data necessary for proper medical evaluations and diagnoses, to ensure that proper treatment is administered, and to maintain continuity of medical care.

c. To provide an accurate medical history of the total health care and medical treatment received by the individual as well as job and/or hazard exposure documentation and health monitoring in relation to health status and claims of the individual.

d. To enable the planning for further care of the patient.

e. To provide a record of communications among members of the health care team who contribute to the patient's care.

f. To provide a legal document describing the health care administered and any exposure incident.

g. To provide a method for evaluating quality of health care rendered and job-health-protection including engineering protection provided, protective equipment worn, workplace monitoring, and medical exam monitoring required by OSHA or by good practice.

h. To ensure that all relevant, necessary, accurate, and timely data are available to support any medically-related employment decisions affecting the subject of the records, (e.g., in connection with fitness-for-duty and disability retirement decisions).

i. To document claims filed with and the decisions reached by the OWCP and the individual's possible reemployment rights under statutes governing that program.

j. To document employee's reporting of on-the-job injuries or unhealthy or unsafe working conditions, including the reporting of such conditions to the OSHA and actions taken by that agency or by the employing agency.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

These records and information in these records may be used:

a. To disclose information to the Department of Labor, Veterans Administration, Social Security Administration, or a national, State, or local social security type agency, when necessary to adjudicate a claim (filed by or on behalf of the individual) under a retirement, insurance, or health benefit program.

b. To disclose information to a Federal, State, or local agency to the extent necessary to comply with laws governing reporting of communicable diseases.

c. To disclose information to another Federal agency, to a court, or a party in litigation before a court or in an administrative proceeding being conducted by a Federal agency, either when the government is a party to a judicial proceeding or in order to comply with the issuance of a subpoena.

d. To disclose in response to a request for discovery or for appearance of a witness, information that is relevant to the subject matter involved in a pending judicial or administrative proceeding.

e. To disclose pertinent information to the appropriate Federal, State, or local agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order when the disclosing agency becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation.

f. To disclose information to the Office of Management and Budget at any stage in the legislative coordination and clearance process in connection with private relief legislation as set forth in OMB Circular No. A-19.

g. To disclose information to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

h. To disclose information to officials of the Merit Systems Protection Board including the Office of Special Counsel, the Federal Labor Relations Authority and its general counsel, the Equal Employment Opportunity Commission, arbitrators, and hearing examiners to the extent necessary to carry out their authorized duties.

i. To disclose information to survey team members from the Joint Commission on Accreditation of Hospitals (JCAH) when requested in connection with an accreditation review, but only to the extent that the information is relevant and necessary to meet the JCAH standards.

j. To disclose information to the National Archives and Records Service in records management inspections conducted under authority of 44 U.S.C. 2904 and 2906.

k. To disclose information to health insurance carriers contracting with the Office of Personnel Management (hereafter referred to as "the Office") to provide a health benefits plan under the Federal Employees Health Benefits Program information necessary to verify eligibility for payment of a claim for health benefits.

l. By the agency maintaining or responsible for generating the records to locate individuals for health research or survey response and in the production of summary descriptive statistics and

analytical studies (e.g., epidemiological studies) in support of the function for which the records are collected and maintained. While published statistics and studies do not contain individual identifiers, in some instances the selection of elements of data included in the study might be structured in such a way as to make the data individually identifiable by inference.

m. To disclose information to the Office of Federal Employees Group Life Insurance that is relevant and necessary to adjudicate claims.

n. To disclose information, when an individual to whom a record pertains is mentally incompetent or under other legal disability, to any person who is responsible for the care of the individual, to the extent necessary.

o. To disclose to the agency-appointed representative of an employee all notices, determinations, decisions, or other written communications issued to the employee, in connection with the examination ordered by the agency under:

(1) Medical evaluation (formerly Fitness for Duty) examinations procedures; or

(2) Agency-filed disability retirement procedures.

p. To disclose to a requesting agency, organization, or individual the home address and other information concerning those individuals who it is reasonably believed might have contracted an illness or been exposed to or suffered from a health hazard while employed in the Federal work force.

q. To disclose information to a Federal agency, in response to its request or at the initiation of the agency maintaining the records, in connection with the retention of an employee, the issuance of a security clearance, the conducting of a suitability or security investigation of an individual, the classifying of jobs, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, or the lawful, statutory, administrative, or investigative purposes of the agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

r. To disclose to any Federal, State, or local government agency, in response to its request or at the initiation of the agency maintaining the records, information relevant and necessary to the lawful, statutory, administrative, or investigatory purpose of that agency as it relates to the conduct of job related epidemiological research or the assurance of compliance with Federal, State, or local government laws on health and safety in the work environment.

s. To disclose to officials of labor organizations recognized under 5 U.S.C. Chapter 71, analysis using exposure or medical records and employee exposure records, in accordance with the records access rules of the Department of Labor's OSHA, and subject to the limitations at 29 CFR 1910.20(e)(2)(iii)(B).

POLICIES AND PRACTICES OF STORING, RETRIEVING, SAFEGUARDING, AND RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders, on microfiche, in automated record systems, and on file cards, X-rays, or other medical reports and forms.

RETRIEVABILITY:

Records are retrieved by the employee's name, date of birth, social security number, or any combination of those identifiers.

SAFEGUARDS:

Records are stored in locked file cabinets or locked rooms. Automated records are protected by restricted access procedures and audit trails. Access to records is strictly limited to agency officials with a bona fide need for the records.

RETENTION AND DISPOSAL:

Some records are retained for the duration of employment with a given agency. Other records are retained for the duration of Federal employment, plus 30 years. Records are destroyed by shredding, burning, or by erasing the disk.

SYSTEM MANAGER AND ADDRESS:

Assistant Director for Workforce Information, Compliance and Investigations Group, U.S. Office of Personnel Management, Room 5415, 1900 E Street, NW, Washington D.C. 20415.

NOTIFICATION PROCEDURE:

Individuals wishing to inquire whether this system of records contains records on them should follow the appropriate procedure listed below.

a. Current employees. Current employees should contact their employing agency's personnel, dispensary, health, safety, medical, or other designated office responsible for maintaining the records, as identified in the agency's internal issuance covering this system. Individuals must furnish such identifying information as required by the agency for their records to be located and identified.

b. Former employees. Former employees should contact their former agency's personnel, dispensary, health, safety, medical, or other designated

office responsible for maintaining the records, as identified in the agency's internal issuance covering this system. Additionally, for access to their EMF, they should submit a request to the Office's regional office nearest their residence. (See list of the Office's regional and area office addresses in the Appendix.) Individuals submitting requests to the Office's regional and area offices must submit the following information for their records to be located and identified:

1. Full name.
2. Date of birth.
3. Social security number.
4. Agency name, dates, and location of last Federal service.

RECORDS ACCESS PROCEDURE:

a. Current employees should contact the appropriate agency office as indicated in the "Notification Procedure" section and furnish such identifying as required by the agency in order to locate and identify the records sought.

b. Former employees should contact the appropriate agency office as indicated in the Notification Procedure section and furnish such identifying information as required by the agency in order to locate and identify the records sought. Former employees may also submit a request to the Office's regional or area office nearest their residence for access to their EMF. (See list of the Office's regional and area office addresses in the Appendix.) When submitting a request to the Office, the individual must furnish the following information in order to locate and identify the record sought:

1. Full name.
2. Date of Birth.
3. Social Security number.
4. Agency name, date, and location of last Federal service.
5. Signature.

c. Individuals requesting access must also comply with the Office's Privacy Act regulations on verification of identify and access to records (5 CFR 297.201 and 297.203).

CONTESTING RECORDS AND PROCEDURE:

Since medical practitioners often provide differing but equally valid medical judgments and opinions when making medical evaluations of an individual's health status, review of requests from individuals seeking amendment of their medical records, beyond correction and updating of the records, will be limited to consideration of including the differing opinion in the record rather than attempting to determine whether the original opinion is accurate.

Individuals wishing to amend their records should:

a. For current employee, contact the appropriate agency office identified in the Notification Procedure section and furnish such identifying information as required by the agency in order to locate and identify the records to be amended.

b. For a former employee, contact the appropriate agency office identified in the Notification Procedure section and furnish such identifying information as required by the agency in order to locate and identify the record to be amended. Former employees may also submit such a request to amend records in their EMF to the system manager. When submitting a request to the system manager, the individual must furnish the following information in order to locate and identify the records to be amended:

1. Full name.
2. Date of Birth.
3. Social security number.
4. Agency name, date, and location of last Federal service.
5. Signature.

c. Individuals seeking amendment of their records must also follow the Office's Privacy Act regulations on verification of identity and amendment of records (5 CFR 297.201 and 297.208).

RECORDS SOURCE CATEGORIES:

Records in this system are obtained from:

- a. The individual to whom the records pertain.
- b. Agency employee health unit staff.
- c. Federal and private sector medical practitioners and treatment facilities.
- d. Supervisors/managers and other agency officials.
- e. Other agency records.

Appendix

CHICAGO REGION

John Kluczynski Building, 230 South Dearborn Street, Chicago, IL 60604

Area Offices

Illinois—219 South Dearborn Street, Chicago, IL 60604

Indiana—U.S. Courthouse and Federal Building, 46 East Ohio Street, Indianapolis, IN 46204

Michigan—477 Michigan Avenue, Room 565, Detroit, MI 48226

Minnesota—Federal Building, Room 501, Fort Snelling, Twin Cities, MN 55111

Ohio—U.S. Courthouse and Federal Building, Room 507, 200 West 2nd Street, Dayton, OH 45402

DENVER REGION

Building 20, Denver Federal Center, Denver, CO 80225

Area Offices

None

DALLAS REGION

1100 Commerce Street, Dallas, TX 75242

Area Offices

Louisiana—Federal Building, 610 South Street, New Orleans, LA 70130

New Mexico—421 Gold Avenue, SW, Albuquerque, NM 87102

Oklahoma/Arkansas—200 5th Street, NW, Oklahoma City, OK 73102

Texas—643 East Durango Blvd., San Antonio, TX 78205

NEW YORK REGION

Jacob K. Javits Federal Building, 26 Federal Plaza, New York, NY 10278

Area Offices

New Jersey—Peter W. Rodino, Jr. Federal Building, 970 Broad Street, Newark, NJ 07102

New York—U.S. Courthouse and Federal Building, 100 South Clinton Street, Syracuse, NY 13260

Puerto Rico—Federico Degetau Federal Office Building, Carlos E. Chadrón Street, Hato Rey, PR 00918

PHILADELPHIA REGION

William J. Green, Jr. Federal Building, 600 Arch Street, Philadelphia, PA 19106

Area Offices

Maryland—Edward A. Garmatz Federal Building and Courthouse, 101 West Lombard Street, Baltimore, MD 21201

Pennsylvania—Federal Building, 1000 Liberty Avenue, Pittsburgh, PA 15222

Virginia—Federal Building, 200 Granby Mall, Norfolk, VA 23510

ST. LOUIS REGION

300 Old Post Office Building, 815 Olive Street, St. Louis, MO 63103

Area Offices

Kansas—120 South Market Street, Wichita, KS 67202

Missouri—East 12th Street, Kansas City, MO 64106

SAN FRANCISCO REGION

525 Market Street, 23rd Floor, San Francisco, CA 94105

Area Offices

Arizona—522 North Central Avenue, Phoenix, AZ 85004

California—845 South Figueroa Street, Los Angeles, CA 90017

1029 J Street, Room 202, Sacramento, CA 95814

880 Front Street, San Diego, CA 92188

Hawaii—300 Ala Moana Blvd., P.O. Box 50028, Honolulu, HI 96850

SEATTLE REGION

Federal Building, 26th Floor, 915 2nd Avenue, Seattle, WA 98174

Area Offices

Alaska—Federal Building and Courthouse, 700 C Street, Box 22, Anchorage, AK 98513

Oregon—Federal Building, Room 376, 1220 3rd Street, SW, Portland, OR 97204

ATLANTA REGION

Richard B. Russell Federal Building, 75 Spring Street, SW, Atlanta, GA 30303

Area Offices

Alabama—Southern Building, 806
Governors Drive, SW., Huntsville, AL 35801
Florida—Federal Building, 80 North Hughey
Avenue, Orlando, FL 32801
North Carolina—310 New Bern Avenue, P.O.
Box 25069, Raleigh, NC 27611
South Carolina—Federal Office Building, 334
Meeting Street, Charleston, SC 29403
Tennessee—100 North Main Building,
Memphis, TN 38103

BOSTON REGION

John W. McCormack Post Office and
Courthouse, Boston, MA 02109

Area Offices

Connecticut—Federal Building, 450 Main
Street, Hartford, CT 06103
Massachusetts—3 Center Plaza, Boston, MA
02108
New Hampshire—Federal/Post Office
Building, Portsmouth, NH 03801

[FR Doc. 85-9285 Filed 4-16-85; 8:45 am]

BILLING CODE 6325-01-M

**SECURITIES AND EXCHANGE
COMMISSION**

[Release No. 34-21936; SR-Amex-85-7]

**Self-Regulatory Organizations;
American Stock Exchange, Inc.; Notice
of Filing of Proposed Rule Change and
Order Granting Accelerated Approval
of Proposed Rule Change**

April 11, 1985.

On March 22, 1985, the American Stock Exchange, Inc. ("Amex") submitted a proposed rule change, pursuant to Section 19(b) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² to amend Amex Rule 959 to permit the entry of opening orders in the cabinet, at a limit price of \$1.00 per contract, under certain circumstances. Currently, Amex Rule 959 permits cabinet orders to be entered for closing transactions only. Under the proposed rule change, specialists shall effect all cabinet transactions by pairing closing purchase or sale orders which have been placed in the cabinet or, provided there are no closing purchase or sale orders in the cabinet to be paired, by pairing closing purchase or sale orders in the cabinet with opening purchase or sale orders. The proposed rule change would permit specialists, customers, firms and traders to enter opening orders only in cases where closing orders already exist in the cabinet. For example, under the proposal, if the cabinet already contains a closing sell order but no closing buy order, then a person may enter an

opening buy order in the cabinet, and the closing sell order will be executed.

Specialists effect cabinet transactions as an accommodation to investors by pairing off closing purchase and sale orders. A closing order will remain unexecuted, however, if there is no closing cabinet order with which it can be paired. The Amex states that the purpose of the proposed rule change is to facilitate the closing out of cabinet orders, by permitting opening orders to be paired with closing orders in the cabinet under certain circumstances. Amex states that the statutory basis of the proposed rule change is section 6(b)(5) of the Act.

The Commission is publishing this release to solicit comment on the proposed rule change. Persons interested in commenting on the proposal should submit six copies of their comments within 21 days from the date of publication of this notice in the *Federal Register*. Comments should be sent to the Secretary of the Commission, 450 Fifth Street NW., Washington, D.C. 20549. Copies of the proposed rule change, and all documents relating to the proposed rule change, except those that may be withheld from the public pursuant to 15 U.S.C. 552, are available for inspection and copying at the Commission's Public Reference Room. Copies of the filing also are available at the Amex.

The Commission finds that the proposed rule change may facilitate the closing out of cabinet orders and thereby accommodate investors who wish to close out positions in inactive, out-of-the-money options series for which there are no displayed bids or offers at the lowest fractional price per contract. For this reason, the Commission finds that the proposed rule change is consistent with the requirements of the Act applicable to a national securities exchange and, in particular, the requirements of Section 6.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof in that the proposal is substantially similar to a rule change proposed by the Philadelphia Stock Exchange, Inc. ("Phlx") and recently approved by the Commission.³ No comments were submitted in response to the Phlx rule proposal.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change is approved.

³ See File No. SR-Phlx-84-20, Securities Exchange Act Release Nos. 21390 (October 10, 1984), 49 FR 40752 (October 17, 1984) and 21515 (November 21, 1984), 49 FR 46859 (November 28, 1984).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

John Wheeler,
Secretary.

[FR Doc. 85-9286 Filed 4-16-85; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-21929; SR-CBOE-85-1, SR-AMEX 85-6]

**Self-Regulatory Organizations;
Chicago Board Options Exchange,
Incorporated, and American Stock
Exchange, Inc., Order Granting
Approval to Proposed Rule Change
and Notice of and Order Granting
Accelerated Approval to Proposed
Rule Change**

The Chicago Board Options Exchange, Incorporated ("CBOE") and the American Stock Exchange, Inc., have submitted proposed rule changes, on January 24, and March 22, 1985, respectively, pursuant to Section 19(b) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² to codify certain policies and amend others concerning new options series.³ The Commission solicited comment on the CBOE proposal, but received none.⁴

**I. Description of the Proposals, Their
Purpose and Statutory Basis**

Both CBOE's and Amex's proposed rule changes would amend their respective rules to allow: (1) Strike price intervals of \$2.50 for individual stock options with strike prices of \$25.00 or less; and (2) the addition of series of individual stock options until the first calendar day of the month in which the options expires, or until the fifth business day prior to expiration in "unusual market conditions."⁵

¹ 15 U.S.C. 78e(b) (1964).

² 17 CFR 240.19b-4 (1984).

³ On February 20, 1985, CBOE submitted Amendment No. 1 to the proposed rule change, unrelated to the instant proposal, which was noticed and approved, together with that part of the original proposal which was only notice in Securities Exchange Act Release No. 21794 (February 26, 1985), 50 FR 8691 (March 4, 1985) and which is being approved herein.

⁴ Because the Amex proposal is substantially similar to the CBOE proposal, it was not separately noticed for comment.

⁵ By letter from Heidi Lift, Staff Attorney, Options Division, Amex, to Heidi Steinberg, Coppola, Attorney, Division of Market Regulation, SEC, dated April 1, 1985, Amex requested the authority to add new equity options series until five business days prior to expiration under unusual market conditions.

¹ 15 U.S.C. 78e(b)(1) (1964).

² 17 CFR 240.19b-4 (1984).

Currently, CBOE's and Amex's rules require strike price intervals of \$5.00 for stocks trading below \$200.00, and \$10.00 for stocks trading at or above \$200.00. In addition the rules of both exchanges allow the introduction of new individual stock option series only until 45 days prior to the series' expiration.

In their respective filings, both exchanges state that permitting strike price intervals of \$2.50 for options with strike prices of less than \$25.00 would enhance depth and liquidity in lower options by making at-the-money or near-the-money puts and calls in these options series more readily available. In this connection, Amex and CBOE noted that the greater availability of at-the-money and near-the-money puts and calls should increase the opportunities for covered call writing and other trading strategies.⁶

In addition, Amex and CBOE note that the portion of their respective proposals which authorize the addition of new option series until the beginning of the month of expiration of new option series until the beginning of the month of expiration is consistent with the policy, recently approved by the Commission, concerning adding new series of index options.⁷ Similarly, the Commission has approved the addition of new index options series until five business days prior to expiration, under unusual market conditions.⁸ In their filings, Amex and CBOE stated that this would provide useful hedging tools in near-term series when a stock makes a dramatic move several weeks before expiration. Currently, when this occurs, investors are offered only deep in-the-money calls and far out-of-the-money puts, or vice versa in the near-term cycle.

II. Solicitation of Comments

The Commission is publishing this Release to solicit comment on the Amex proposed rule change. Persons interested in commenting on this proposal should submit six copies of their comments within 21 days from the date of publication of this notice in the Federal Register. Comments should be

sent to the Secretary of the Commission, 450 5th Street NW., Washington, D.C. 20549. Copies of the proposed rule changes, including amendments, and all documents relating to the proposed rule change, except those that may be withheld from the public pursuant to 15 U.S.C. 552, are available for inspection and copying at the Commission's Public Reference Room. Copies of the filings are also available at the Amex.

III. Approval of Proposals

As indicated above, by using \$2.50 strike price intervals for options on lower priced securities, the proposed rule changes by CBOE and Amex may enhance the depth and liquidity of the market for these options. Similarly, by allowing the introduction of new option series until the beginning of the series' expiration month, the proposals may provide more effective hedging vehicles and further enhance depth and liquidity in the options markets, generally. In this connection, the Commission recognizes that the exchanges recently have amended their rules to expand the number of individual stock option series which may be introduced and maintained at any given time,⁹ and that the instant rule changes would cause further proliferation of new stock option series. Nevertheless, the Commission believes that the narrower strike price intervals for options on stock priced at or below \$25.00 and the introduction of new series until the first calendar day of the expiration month should provide the additional flexibility for hedging and other options trading strategies that has been requested by many market participants.

The Amex proposal also permitted the exchange to introduce and maintain two in-the-money and two out-of-the-money option series until 45 days prior to expiration. (CBOE's proposal contained a similar plan for the introduction and maintenance of more than one in-the-money and out-of-the-money stock option series.)

The Commission believes that the exchanges have struck an appropriate balance between accommodating the needs of market participants and causing an excessive proliferation of option series.¹⁰ Accordingly, for the

reasons stated above, the Commission finds that the proposed rule change is consistent with the requirements of the Act applicable to national securities exchange and, in particular, section 6 and the rules and regulations thereunder. In addition, the Commission finds good cause for approving the Amex's proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof in that CBOE's proposed rule change, which is substantially similar, was published for comment over 30 day ago, and no comments were received in response to that publication.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that both proposed rule changes are approved. For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

John Wheeler,

Secretary.

April 10, 1985.

[FR Doc. 85-9264 Filed 4-16-85; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-21932; SR-NYSE-85-6]

Self-Regulatory Organizations; New York Stock Exchange, Inc.; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change; Relating to the Amendment of Certain NYSE Rules and Practices Concerning Individual Stock Options and Stock Index Options

The New York Stock Exchange, Inc. ("NYSE"), submitted on March 6, 1985, a proposed rule change pursuant to Section 19(b) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² to amend certain NYSE rules and policies concerning the trading of options on individual listed stocks and stock index options.³

I. Description of the Proposals, Their Purpose and Statutory Basis

In pertinent part, the NYSE proposal amends the following rules and policies. The NYSE proposes to amend Rules 700 (a) and (b) and 758 (Supplementary Material, 10) to clarify the definition of Options Floor. In this connection, Rule 700(b) defines "floor" as the Options

⁶ In addition, CBOE indicated that the use of \$2.50 strike price intervals for lower priced securities will help certain member firms obtain favorable tax consequences. Telephone conversation between Frederick M. Kreiger, Assistant General Counsel, CBOE, and Heidi Steinberg Coppola, Attorney, Division of Market Regulation, SEC, April 3, 1985.

⁷ In Securities Exchange Act Release No. 21362 (September 28, 1984), 49 FR 39135 (October 3, 1984), the Commission approved a CBOE rule change allowing the addition of series of index options until the first calendar day of the month in which the series expires.

⁸ See Securities Exchange Act Release No. 21794, *supra*, note 3.

⁹ In Securities Exchange Act Release No. 21644 (January 9, 1985), 50 FR 2360 (January 16, 1985), the Commission approved an Amex proposal narrowing strike price intervals to \$5.00, from \$10.00, for options on stocks whose value is between \$100.00 and \$200.00 per share. Subsequently, the Commission approved a substantially similar proposal for CBOE, Securities Exchange Act Release No. 21794 (February 26, 1985), *supra*, note 3.

¹⁰ See *Cf.* Securities Exchange Act Release Nos. 21644 and 21794, *supra*, notes 10 and 3.

¹ 15 U.S.C. 78b(b) (1984).

² 17 CFR 240.19b-4 (1984).

³ In its filing, the NYSE indicates that in view of the Commission's recent approval of its proposal to trade individual listed stock options (Securities Exchange Act Release No. 21759 (February 14, 1985), 50 FR 7250 (February 21, 1985)), the NYSE is proposing to amend several of its rules to conform its individual stock options rules to those of the other option exchanges.

Floor,⁴ and both paragraphs (a) and (b) indicate that, unless specifically stated otherwise, it is this definition which is to be used in interpreting the NYSE rules governing options transactions.

Amendments to Rule 758.10(b) consist of deletions that clarify which orders must yield priority to orders entered from off the Options Floor. As amended, Rule 758.10(b) indicates that under certain circumstances, all member organizations entering options orders who are in contact with the Options Floor or whose proprietary orders are handled in a manner similar to the order of a Competitive Options Trader ("COT")⁵ present on the floor, are subject to the same restrictions as a COT.⁶

In addition, the proposal amends Rules 703(e) and 717.10(c) concerning closing rotations, to conform these rules to the rules of the Chicago Board Options Exchange, Inc. ("CBOE") and others. As amended, these rules would allow the NYSE to hold closing rotations for expiring listed stock options series on the last trading day prior to the series' expiration date, at the time the last trade is disseminated, in those instances when the last trade is reported after 4:00 p.m.⁷

The proposal also amends NYSE Rule 716 to conform to recent proposed rule changes by CBOE and the American Stock Exchange, Inc. ("Amex"). In particular, the proposal adds a new provision to Rule 716 (Supplementary Material .30), which provides that the NYSE may delist options series with no open interest after notification to member organizations.⁸

⁴ NYSE Rule 700(b)(24A) cross-references Rule 758.10(a), which has been amended to describe the "Options Floor" as "the area where options trading occurs and those areas immediately adjacent used for options trading, such as the booths of floor brokers."

⁵ New subparagraph (b)(i)(E) to Rule 758 also clarifies the Rule by providing that all orders entered by a member or clearing member while they are within the "line-of-sight" of the Options Floor similarly are subject to these restrictions. In its filing, the NYSE states that the characteristics of these orders and the substance of restrictions to which they are subject are not affected by the amendment.

⁶ For example, subparagraphs (b) (i), (ii), and (iii) of NYSE Rule 758 restrict COTS from initiating an exchange transaction in a kind of option in which he is registered for any account in which he has an interest, except under limited circumstances: effecting an exchange option transaction for an account in which he has an interest and executing an off-floor order in an option of the same class having the same expiration date and exercise price during the same trading session, while on the floor; and congregating in a particular option contract if the class is not assigned to the COT and if he has a desire to purchase or sell option contracts in that class for accounts in which he has an interest.

⁷ See CBOE Rule 6.2 (Interpretation .03).

⁸ Securities Exchange Act Release No. 21644 (January 9, 1985), 50 FR 2360 (January 16, 1985). See

In addition, the NYSE proposes to amend Rule 750, subparagraphs (c)(i), (ii) and (iii), respectively, to define spread, straddle, and combination orders to cover adjusted stock option contracts, in a manner consistent with the rules of other options exchanges.⁹ As amended, the rule would allow spread, straddle and combination orders involving different numbers of contracts in each leg to receive the same priority, provided that the same number of shares of the underlying security are the subject of each leg of the spread, straddle or combination order. The NYSE also added subparagraph (c)(v) to this Rule, to define a "stock-option order," similar to certain other exchanges.¹⁰

With respect to options trade comparison procedures, the NYSE proposal amends Rules 764 and 770, by specifying more detailed deadlines and requirements for members to meet when reconciling uncompleted options trades. The NYSE states that these requirements are consistent with the rules of certain other exchanges. In particular, the cut-off time for reconciling uncompleted transactions is extended from 9:00 to 9:45 a.m. to reflect the obligations of Exchange members and member organizations to resolve promptly unmatched trades under amended NYSE Rule 764, Supplementary Material .10 through .50.¹¹ In addition, the new Supplementary Material (.10 through .50) states that during the trade resolution process, verbal commitments are binding on both parties and misrepresentations are inconsistent with just and equitable principles of trade.¹²

The NYSE proposal further amends NYSE Rule 782 to clarify the obligations of holders and writers of index options upon exercise and assignment in a manner consistent with the other exchanges trading index options. In its filing, the NYSE states that the amended language does not substantively change the settlement procedures for index options.

Finally, the proposal amends the NYSE exercise price policies for stock options to conform them to those of other options exchanges in that they would allow: (1) the listing of series with

exercise prices of \$5.00 as long as the series had not met delisting standards; and (2) the listing of strike price intervals of \$5.00 (rather than \$10.00), when the underlying stock price is between \$100 and \$200 (strike price intervals of \$10 would remain unchanged for underlying stocks with prices above \$200).¹³

III. Solicitation of Comments

The Commission is publishing this notice to solicit comment on the NYSE's proposed rule changes. Persons interested in commenting on these proposed changes should submit six copies of their comments within 21 days from the date of publication of this notice in the *Federal Register*. Comments should be sent to the Secretary of the Commission, 450 Fifth Street NW., Washington, D.C. 20549. Copies of the proposed rule changes, including any amendments and documents relating to the proposed change, except those that may be withheld from the public pursuant to 15 U.S.C. 552, are available for inspection and copying at the Commission's Public Reference Room. Copies of the filing also are available at the NYSE.

III. Approval of the Proposals

As indicated above, the NYSE's proposed amendments to their rules and policies concerning stock options and stock index options are substantially similar to those rules of the existing options exchanges, several of which the Commission recently has approved.¹⁴ For the reasons discussed in the orders approving those proposals, the Commission finds that the NYSE proposals are consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange and, in particular, the requirements of Section 6. The Commission finds good cause for approving these proposed rule changes prior to the thirtieth day after the date of publication of notice of filing thereof, in that the NYSE proposal does not present any new or unique issues. In addition, the substance of the amendments described above have been the subject of proposals submitted by the existing options exchanges and approved by the Commission. In this connection, the Commission notes that no adverse comments were received regarding those proposed rule changes.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the

Securities Exchange Act Release No. 21794 (February 26, 1985), 50 FR 8691 (March 4, 1985) (order approving similar rule proposals by the CBOE, Pacific, and Philadelphia Stock Exchanges).

⁹ See e.g., Amex Rule 950(e)(i), (ii), and (iii).

¹⁰ See e.g., CBOE Rule 1.1(ii).

¹¹ See CBOE Rule 6.61 (Interpretations .01-.05).

¹² In addition, Supplementary Material .50 mandates detailed procedures for index options and stock options trading ex-dividend or ex-distribution the next day.

¹³ See Securities Exchange Act Release No. 21644, *supra* note 7.

¹⁴ See note 7, *supra*.

proposed rule changes described above are approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

John Wheeler,

Secretary.

April 10, 1985.

[FR Doc. 85-9285 Filed 4-16-85; 8:45 am]

BILLING CODE 8010-01-M

[Release No. IC-14467 (File No. 812-5697)]

Paine Webber Programmed Amortization Term Securities, Inc.; Application and Opportunity for Hearing

April 11, 1985.

Notice is hereby given that Paine Webber Programmed Amortization Term Securities, Inc. ("Applicant"), 4060 Interfirst Two, Dallas, Texas 75270, filed an application on November 14, 1983, and an amendment thereto on January 28, 1985, for an order, pursuant to Section 8(c) of the Investment Company Act of 1940 ("Act"), exempting Applicant from all provisions of the Act. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below, and to the Act for the complete text of the provisions referred to herein and in the application.

According to the application, Applicant is a wholly-owned, limited purpose finance subsidiary of Paine Webber Incorporated. The Applicant has not engaged and will not engage in any activities other than (i) issuing and selling bonds ("Bonds") under the Indenture (as defined below) collateralized by "fully modified pass-through" mortgage-backed certificates issued and serviced by a mortgage banking company or other financial concern (an "Issuer") and guaranteed by the Government National Mortgage Association ("GNMA Certificates") and acquiring, owning, holding and pledging the related GNMA Certificates, and (ii) issuing and selling obligations ("Obligations") and acquiring, owning, holding and pledging as collateral therefor other mortgage-related instruments. Applicant represents that it will not issue any Bonds or Obligations unless they are rated in the highest bond rating category by two nationally recognized statistical rating agencies.

The Applicant states that it is seeking an order solely for the purpose of eliminating the requirement that it maintain a portion of its assets in "whole pool" GNMA Certificates. Although Applicant may acquire

mortgage-related securities other than GNMA Certificates to collateralize an offering of its debt securities, Applicant agrees that in those cases it will satisfy the "whole pool" requirement.

The Applicant proposes to issue and sell the Bonds in series. Each series of Bonds will be issued pursuant to one or more indentures between the Applicant and a qualified trustee ("Trustee"), as supplemented by one or more supplemental indentures ("Indenture"). The Indenture for each series of Bonds will be qualified under the Trust Indenture Act of 1939. The Bonds of each series will be secured by assignments to the Trustee of collateral consisting of GNMA Certificates, together with the payments thereon, having an outstanding principal balance at the date of issuance of the Bonds of not less than the principal amount of Bonds being issued. The Trustee will have a first priority perfected security interest in all of the collateral pledged to secure each such series of Bonds. The collateral securing each series of Bonds will serve as collateral only for that series of Bonds. The Applicant will not add any GNMA Certificates to, or substitute other GNMA Certificates for, the original GNMA Certificates included in the collateral. Scheduled distributions on the GNMA Certificates together with an initial cash deposit by the Applicant (and, if applicable, reinvestment income) shall be sufficient to make timely payments of interest on the Bonds and to retire each class of Bonds not later than its stated maturity. Reserve funds and other cash held by the Trustee as collateral for the Bonds may only be invested in obligations of the United States or of any agency thereof backed by the full faith and credit of the United States or cash equivalents meeting rating agency requirements. Except in an event of default, the terms of the Bonds will provide bondholders neither the right to request redemption nor the right to compel liquidation of the GNMA Certificates in order to redeem Bonds prior to maturity. The Bonds will be subject to special redemption at 100% of their unpaid principal amount plus accrued interest, if, as a result of substantial prepayments on the GNMA Certificates and low reinvestment yields, the Applicant determines that current interest requirements of the Bonds cannot be met. Any such redemption is limited to a principal amount of Bonds that would otherwise be required to be paid on the next payment date out of such principal receipts. The Bonds are not otherwise subject to call at the option of the Applicant except that a class of Bonds

within a series may be redeemed in whole (but not in part) on any payment date on which the outstanding principal amount of such class of Bonds has declined to 10% or less of the original principal amount of such class.

The Applicant submits that granting the requested exemptive relief is justified in two respects: (1) While investment in "partial pool" GNMA Certificates may raise questions as to whether the investment is technically in a security separate from the underlying mortgage, this distinction has no substantive meaning to the Applicant. Therefore, while there may not be literal compliance with the section 3(c)(5)(C) exclusion from the Act, the Applicant is the type of entity which was intended to be exempt from the Act by virtue of such Section; (2) The Applicant was formed for the limited purpose of issuing debt securities secured by GNMA Certificates and other mortgage-related securities. However, Applicant submits that if it issues debt securities not secured by GNMA Certificates it will comply with the "whole pool" requirement. The Applicant will not trade or deal in securities or engage in any activities other than those incidental to and necessary for such purpose. The debt securities to be offered to the public are low risk securities receiving the highest rating from two nationally recognized rating agencies. Because of these factors, the Applicant is not the type of entity which was intended to be regulated under the Act and its limited activities do not require the protection of the Act. Furthermore, the Applicant submits that there are strong policy reasons for granting the exemptive relief in that its activities supply capital to the secondary mortgage market and thereby facilitate the financing of mortgages, a critical national need.

Notice is further given that any interested person wishing to request a hearing on the application may, not later than May 7, 1985, at 5:30 p.m., do so by submitting a written request setting forth the nature of his interest, the reasons for his request, and the specific issues, if any, of fact or law that are disputed, to the Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of the request should be served personally or by mail upon Applicant at the address stated above. Proof of service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed with the request. After said date an order disposing of the application will be issued unless the Commission orders a

hearing upon request or upon its own motion.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

John Wheeler,
Secretary.

[FR Doc. 85-0268 Filed 4-16-85; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-21935; SR-PSE-85-5]

Self-Regulatory Organizations; Pacific Stock Exchange, Inc.; Order Approving Proposed Rule Change

The Pacific Stock Exchange, Inc. ("PSE"), submitted a proposed rule change pursuant to Section 19(b) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² to amend PSE Rule VI, Sections 36(b) and 79, respectively, to provide a more detailed procedure for closing rotations, and to clarify the bid-ask differential rule. The Commission solicited comment on the proposal, but received none.³

Specially, the proposed rule change would amend section 36(b) to provide PSE with the ability to use trading rotations in additional, limited situations not permissible under PSE's current rules. In this connection, the proposal would permit the use of a trading rotation when a delayed opening or reopening of trading in the underlying security occurs after 12:30 p.m. (San Francisco Time), and when a "fast market" is declared by two PSE Options Floor Officials, in accordance with guidelines established by PSE in Options Floor Procedure Advice G-9. The decision to employ a trading rotation after 12:30 p.m. would be publicly announced on the trading floor at least 10 minutes prior to the commencement of such rotation, and only one trading rotation may be commenced in any given options class after 1:00 p.m.

As a related matter, when a closing rotation is necessary the PSE Order Book Official would be required to use a single price closing procedure. This would prohibit free trading after the closing rotation so that all trades would be required to be executed at the established closing price. In addition, the proposed rule change would provide that public customer orders receive the same priority as they do during opening rotations, (i.e., priority over market-makers, firm proprietary orders, etc.).

Currently, PSE Rule VI, section 36(b) only authorizes the use of a closing rotation if trading in the underlying security either opens or reopens after 12:45 p.m. In addition, the rule currently does not specify whether a single price procedure should be used, rather than free trading in each series, or whether customer orders will receive the same priority they now have in connection with opening rotations.

In its filing, PSE indicated that it is amending the trading rotation rule to provide for its expanded use, in part, as a result of PSE's recent experience with the existence of a fast market. In addition, PSE indicated that further amendment to the trading rotation rule is necessary to clarify that the Order Book Official is required to use a single price procedure and that public customer orders have the same priority over market-maker and others during the extraordinary trading rotations, as they do now in the ordinary opening and closing rotations. Finally, PSE stated that new section 36(b) of Rule VI is consistent with the rules of CBOE and other options exchanges.⁴

With respect to PSE Rule VI, section 79, the proposed rule change would clarify the bid-ask differentials by conforming the language in Commentary .02 to the language in paragraph (b)(1) of that Rule. Paragraph (b)(1) of section 79 uses the current "bid" for an options series as the reference point for establishing the bid-ask differential, and defines the maximum bid-ask differential in terms of the bid price (i.e., the difference shall be no more than $\frac{1}{4}$ of \$1 between the bid and the offer for each option contract for which the bid is \$.50 or less). Commentary .02 of Section 79 repeats the bid-ask differential formula contained in paragraph (b)(1), except that it uses the "last sale" of the option as the reference point to establish the bid-ask differential, instead of the current "bid" price. To make the Commentary consistent with the Rule, the proposed rule change would delete the "last sale" language from Commentary .02, and use the current "bid" price as the sole reference point in determining the bid-ask differential for an option.

In its filing, PSE indicated that in July 1984, Section 79 was amended to reduce the maximum bid-ask differentials in order to create tighter options markets. PSE noted, however, that "in a recent effort to circumvent the tighter markets, some market makers have seized upon

the 'last sale' language contained in Commentary .02 to lay wider markets in options that trade irregularly." As a result, the Options Floor Trading Committee, on November 13, 1984, directed the PSE staff to clarify the bid-ask differential Rule and Commentary, as described above. In this connection, PSE also stated that "the clear intent of Section 79 is that the current 'bid,' as the best reflection of the existing market, should be the reference point for the bid-ask differential, not a last sale which may be hours or days old."

PSE stated that it believes the proposed rule change is consistent with the requirements of the Securities Exchange Act of 1934 ("Act") and the rules and regulations thereunder in that the new closing procedure will ensure customer priority when a rotation is used, and the amendment of Section 79 will guarantee that the narrower bid-ask differentials can be enforced under all market conditions. Therefore, PSE stated that the proposed rule change is consistent with section 6(b)(5) of the Act.

By authorizing the use of trading rotations in connection with delayed openings and reopenings, and fast markets, as described above, the Commission believes that the proposed rule change should help enable the PSE to maintain fair and orderly markets in these unusual circumstances. Similarly, by clarifying that the bid-ask differential rule makes the current bid and not the last-sale price the reference point for the bid-ask differential formula, in conformity with PSE's original intent, the proposed rule change also should help PSE maintain tighter markets. In addition, to the extent this clarification would prohibit member firms from circumventing the intent of the rule, and require all member firms to operate under the same principle, the Commission believes the proposed rule change also would promote just and equitable principles of trade. Accordingly, the Commission finds that the PSE proposal is consistent with the requirements of the Act and the rules and regulations thereunder applicable to national securities exchanges. In particular, the Commission finds that the proposal is consistent with Section 6 of the Act.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the above-mentioned rule change be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

¹ 15 U.S.C. 78s(b) (1984).

² 17 CFR 240.19b-4 (1984).

³ The proposed rule change was noticed in Securities Exchange Act Release No. 21799 (March 1, 1985), 50 FR 9340 (March 7, 1985).

⁴ The text of the proposed rule change is modeled after a similar rule of the Chicago Board Options Exchange, Inc. ("CBO") (CBOE Rule 6.2, Commentary .02).

April 11, 1985.

John Wheeler,

Secretary.

[FR Doc. 85-9267 Filed 4-16-85; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-21931; SR-NYSE-85-5]

**Self-Regulatory Organizations;
Proposed Rule Change by the New
York Stock Exchange, Inc.; Notice of
Filing of Proposed Rule Change; Order
granting Accelerated Approval of
Proposed Rule Change; Relating to
Opening New Options Series.**

**I. Description of the Proposals and Their
Purpose**

The New York Stock Exchange, Inc. ("NYSE") submitted a proposed rule change on March 6, 1985, pursuant to Section 19(b) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² to amend NYSE Rule 703, Supplementary Material .30, regarding the opening of new options series and exercise prices.³

The proposed rule change would amend NYSE Rule 703, Supplementary Material .30, to allow the addition of stock group index options series in the near-term expiration month until five days prior to the current month's expiration.⁴ In addition, the proposal would allow the NYSE to list at least two in-the-money, to out-of-the-money and one at-the-money exercise prices for index options upon introduction of a new expiration month, and to add strike prices in response to changes in the underlying index so as to maintain two in-the-money, two out-of-the-money and one at-the-money strike prices at all

times until the last day for adding new strike prices.⁵

The NYSE proposes to maintain two in-the-money and two out-of-the-money strikes by adding strike prices that are two price intervals (or \$10) above (or below) the underlying index value when the index value rises (or falls) to an existing strike price.⁶ For example, under this proposal, when an index rises to 95, strike prices of 105 could be added. An additional strike price would be authorized in unusual market conditions.

As the NYSE explains in its filing, with regard to NYSE Rule 703, Supplementary Material .30(a), the purpose of the proposed rule change is to allow the Exchange greater flexibility and efficiency in adding new option series in response to changes in an index value. The NYSE states that the change will assist in preventing situations where a major movement in an index value has left no series at-the-money or slightly out-of-the-money in the near-term expiration month. With regard to subparagraph (c), the NYSE explains that it is necessary to maintain at least two, rather than one, in-the-money and out-of-the-money series in all expiration months open for trading (in addition to one at-the-money series) to provide flexibility for investors during volatile market periods.

The NYSE further states that these amendments derive support from the arguments made in a previous NYSE filing (File No. SR-NYSE-84-2), which proposed a trigger price for the addition of new strike prices of 2.5 points lower or higher than the highest or lowest exercise price then trading and the introduction of series of index options up to the beginning of the calendar month in which the options series expires.⁷ In that filing, the NYSE

demonstrated the manner in which, under existing policy, the Exchange may be deprived of its ability to trade in-the-money and out-of-the-money series which may unjustifiably restrict an investor's ability to trade and transfer risk through strategies using the Exchange's cash-settled index options.⁸ In addition, in the present filing, the NYSE states that its proposal is consistent with the policy the Commission recently approved for trading additional series of index options,⁹ and that the NYSE proposal complies with the statutory requirements of Section 6(b)(5) of the Act.

Finally, the NYSE proposal eliminates from the provision concerning the trigger price for adding new option series [Supplementary Material .30(b)] any reference to stock index options, thereby making this provision exclusively applicable to individual stock options.¹⁰ As amended, this provision would allow the NYSE to introduce series with new exercise prices and subsequently add new strike prices when the price of the underlying stock coincides with the exercise price of the series that are currently open for trading.¹¹

The NYSE are equally applicable to both parts of the proposal. Securities Exchange Act Release No. 21067 (June 19, 1984), 49 FR 26173 (June 26, 1984).

⁸ See File No. SR-NYSE-84-2, Item 3, at 5-17. Similarly, as described above, a recent order approving the Amex's proposal to narrow strike price intervals for stock options and to allow one at-the-money and two in-the-money and out-of-the-money strike prices for index options, the Commission determined that the Amex proposal "strikes an appropriate balance by accommodating market participants without causing excessive proliferation of options series." See Securities Exchange Act Release No. 21644, *supra* note 3.

⁹ See Securities Exchange Act Release Nos. 21644 and 21794, *supra* note 3.

¹⁰ This section provides that, "[o]rdinarily, the Exchange will introduce series with new exercise prices when the price of the underlying stock coincides with the exercise price of the series that are currently open for trading." NYSE Rule 703, Supplementary Material .30(b), as amended.

¹¹ The CBOE recently codified its policy with regard to the introduction and subsequent addition of series of individual stock options to provide that if the underlying stock is within 2% of a strike price interval, three strike prices would be listed upon the introduction of a new expiration month, one strike price closest to the underlying stock price and one strike price above and below that one. If the price of the underlying stock is more than 2% away from a strike price interval, two strike prices, one above and one below the strike price, would be listed upon the introduction of a new expiration cycle. Similar to NYSE's proposed rule change, CBOE's rule provides that when the price of the underlying stock rises (or falls) to an existing strike price, a new strike price one interval above (or below) would be added. See Securities Exchange Act Release No. 21794, *supra* note 3.

¹ 15 U.S.C. 78s(b)(1) (1984).

² 17 C.F.R. 240.19b-4 (1984).

³ With respect to stock index options, the NYSE proposal is substantially similar to recent proposals by the American ("Amex"), Chicago Board Options ("CBOE"), and Pacific ("PSE") Stock Exchanges. The Commission solicited comment on all of these proposals but received none. See Securities Exchange Act Release Nos. 21644 (January 9, 1985), 50 FR 2360 (January 16, 1985) (Amex); and 21794 (February 26, 1985), 50 FR 8691 (March 4, 1985) (CBOE and PSE). With respect to individual stock options, the NYSE proposal substantially conforms to Amex's rules.

⁴ Currently, the NYSE allows the listing of new strike prices for index options up to the first calendar day of the month in which the series expires. Because index options expire on the third Friday following the third Friday of their expiration month, this means that under NYSE's current rules new strike prices cannot be added for the last 16-21 calendar days prior to the expiration of the series. The NYSE proposal does not amend this provision with regard to individual stock options, but rather continues to provide that for stock options additional series may be introduced until 45 days prior to the expiration of the option.

⁵ Currently, the NYSE allows the listing of one in-the-money, one out-of-the-money and one at-the-money strike price for index options upon the introduction of a new expiration month, and adds new strike prices thereafter so as to maintain one in-the-money, one out-of-the-money and one at-the-money strike price at all times prior to the expiration of the series. Thus, under the NYSE's existing policy, when the index value rises to 95, a strike price of 100 would be added.

⁶ As a related matter, in File No. SR-NYSE-85-6, submitted to the Commission simultaneously with the instant proposal, the NYSE proposes to amend its rules to allow it to delist series with no open interest; thus should the NYSE list a new series in anticipation of a large market movement that does not materialize, it would be able to delist that series if it attracts no trading interest. The Commission recently approved a substantially identical proposal by Amex. See Securities Exchange Act Release No. 21644, *supra* note 3.

⁷ Although the Commission only approved the portion of this proposal concerning the introduction of new index options series, the arguments cited by

II. Solicitation of Comments

The Commission is publishing this notice to solicit comment on the NYSE's proposed rule changes described above. Persons interested in commenting on the proposed rule changes should submit six copies of their comments within 21 days from the date of publication of this notice in the *Federal Register*. Comments should be sent to the Secretary of the Commission, 450 Fifth Street, N.W., Washington, DC 20549. Copies of the proposed rule changes, and any amendments and documents relating to the proposed rule changes, except those that may be withheld from the public pursuant to 15 U.S.C. 552, are available for inspection and copying at the Commission's Public Reference Room. Copies of the filing are also available at the NYSE.

III. Approval of the NYSE Proposal

As indicated above, the NYSE's proposal concerning stock index options is essentially identical to various provisions of Amex, CBOE and PSE rules which the Commission recently approved. In addition, the stock option portion of the NYSE proposal is substantially similar to CBOE's rules regarding the introduction and addition of strike price intervals for equity options. For the reasons discussed in the orders approving those proposed rule changes,¹⁴ the Commission finds that the NYSE's proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to national securities exchanges, and, in particular, the requirements of Section 6. The Commission finds good cause for approving this proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof, in that over 30 days ago, in two separate instances, the Commission published orders requesting comment and approving substantially identical proposals submitted by Amex, CBOE and PSE, and no adverse comments were submitted in response to those publications.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change described above is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

¹⁴ See note 3, *supra*.

Dated: April 10, 1985.

John Wheeler,
Secretary.

[FR Doc. 85-9263 Filed 4-16-85; 8:45 am]

BILLING CODE 8010-01-M.

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirement Under OMB Review

ACTION: Notice of reporting and recordkeeping requirement submitted for OMB review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35, agencies are required to submit proposed reporting and recordkeeping requirement to OMB for review and approval, and to publish notice in the *Federal Register* that the agency has made such a submission.

DATE: Comments must be received on or before May 10, 1985. If you anticipate commenting on a submission but find that time to prepare will prevent you from submitting comments promptly, advise the OMB reviewer and the Agency Clearance Officer of your intent as early as possible before the comment deadline.

Copies

Copies of the form, request for clearance (S.F. 83), supporting statement, instructions, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer. Submit comments to the Agency Clearance Officer and the OMB Reviewer.

FOR FURTHER INFORMATION CONTACT:

Agency Clearance Officer: Elizabeth M. Zaic, Small Business Administration, 1441 L St., NW., Room 200, Washington, D.C. 20416 Telephone: (202) 653-8538

OMB Reviewer: Kenneth B. Allen, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3235, New Executive Office Building, Washington, D.C. 20503, Telephone: (202) 395-3785

Information Collection Submitted for Review

Title: Informal Investor Survey in the Eastern Great Lakes
Frequency: One-time, non recurring
Description of Respondents: Information is needed to identify investors characteristics and their types of business investments in the Eastern Great Lakes area for small business advocacy policy.

Annual Responses: 383

Annual Burden Hours: 165

Type of Request: Extension

Dated: April 10, 1985.

Richard Vizachero

Acting Chief, Information Resources Management Branch, Small Business Administration.

[FR Doc. 85-9168 Filed 4-16-85; 8:45 am]

BILLING CODE 8025-01-M

[Application No. 03/03 0178]

DC Bancorp Venture Capital Co.; Application for a License To Operate as a Small Business Investment Company

Notice is hereby given that an application has been filed with the Small Business Administration (SBA) pursuant to § 107.102 of the Regulations governing SBIC's (13 CFR 107.102 (1984)) under the name of DC Bancorp Venture Capital Company, 1801 "K" St., NW., Washington, D.C. 20001 for a license to operate in the Washington, D.C. area as a Corporation under the provisions of the Small Business Investment Act of 1958 (Act), as amended (15 U.S.C. 661 et seq.).

The Applicant will begin operations with private capital of \$1,500,000.

The officers, directors and their shareholders of the Applicant are as follows:

Allan A. Weissburg, 6800 Fleetwood Rd. McLean, VA 22101—President, General Manager
Thomas D. Walsh, Suite 490, 1050 Connecticut Ave., Washington, D.C. 20036—Vice President, Director
Albert A. D'Alessandro, 1801 "K" St., NW., Washington, D.C. 20006—Secretary, Treasurer
Joanne McDowell, 1801 "K" St., NW., Washington, D.C. 20006—Assistant Secretary
Jeffrey R. Reider, Suite 350, 919 18th St., NW., Washington, D.C. 20006—Director
John Cralle, 4922 Fairmont Ave., Bethesda, MD 20814—Director
DC Bancorp Investment Co., 1801 "K" St., Washington, D.C. 20006—1/5 Shareholder

Money Management Associates, 4922 Fairmont Ave. Bethesda, MD 20814—1/5 Shareholder
IMW Investment Partnership, Suite 490, 1050 Connecticut Ave., NW., Washington, D.C. 20036—1/5 Shareholder

Matters involved in SBA's consideration of the application include the general business reputation and character of the proposed owners and management, and the probability of successful operations of the company

under their management, including adequate profitability and financial soundness, in accordance with the Small Business Investment Act of 1958, as amended, and the SBA Rules and Regulations.

Notice is further given that any person may, not later than 30 days from the date of publication of this Notice, submit written comments on the proposed Applicant. Any such communication should be addressed to the Deputy Associate Administrator for Investment, Small Business Administration, 1441 "L" St., NW., Washington, D.C. 20416.

A copy of this notice shall be published in a newspaper of general circulation in Washington, D.C.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: April 10, 1985.

Robert G. Lineberry,

Deputy Associate Administrator for Investment.

[FR Doc. 85-9172 Filed 4-16-85; 8:45 am]

BILLING CODE 8025-01-M

[License No. 02/02-5485]

Formosa Capital Corp.; Application for a License to Operate as a Small Business Investment Company

An application for a license to operate as a small business investment company (SBIC) under the provisions of section 301(d) of the Small Business Investment Act of 1958, as amended (the Act), (15 U.S.C. 661 *et seq.*), has been filed by Formosa Capital Corp., 605 King George Post Road, Fords, New Jersey 08863, with the Small Business Administration (SBA), pursuant to 13 CFR 107.102 (1985).

The officers, directors and shareholders of the Applicant are as follows:

Name and address	Title of relationship	Percent of ownership
Philip Sheng-Fu Chen, 17 Arthur Place, Montville, NJ 07045	Chairman of the Board, President, Director	30
Maurice Shun-Nan Hsu, M.D., 11 Greenwood Road, Old Tappan, NJ 07675	Treasurer, Secretary, Director	15
Walter Shih-Shiang Ho, 3rd Floor, Lane 157, Hsin Shen South Road Sec. 1, Taipei, Taiwan	Director	30
Chie Hsiung Cheng, 3 Fl., No. 41, Lane 621, Pei-An Road, Taipei, Taiwan	Director	15
Wen Ling Lee, 97 Taylor Drive, Closter, NJ 07624	Director	10

The Applicant, a New Jersey corporation, will begin operations with a capitalization of \$1,000,000 and will

conduct its operations in the State of New Jersey and the New York City Metropolitan area.

As an SBIC licensed to operate under section 301(d) of the Act, the Applicant will provide financial and managerial assistance solely to small business concerns which will contribute to a well-balanced national economy by facilitating ownership in such concerns by persons whose participation in the free enterprise system is hampered because of social or economic disadvantages.

Matters involved in SBA's consideration of the Application includes the general business reputation and character of the proposed owners and management, and the probability of successful operation of the Applicant under their management, including adequate profitability and financial soundness, in accordance with the Act and the SBA Rules and Regulations.

Notice is hereby given that any person may, not later than 30 days from the date of publication of this notice, submit written comments on the proposed SBIC to the Deputy Associate Administrator for Investment, Small Business Administration, 1441 L Street, NW., Washington, D.C. 20416.

A copy of this notice shall be published in a newspaper of general circulation in Fords, New Jersey.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: April 9, 1985.

Robert G. Lineberry,

Deputy Associate Administrator for Investment.

[FR Doc. 85-9170 Filed 4-16-85; 8:45 am]

BILLING CODE 8025-01-M

[Application No. 05/05-0203]

Sea Gate Small Business Investment Co.; Application for a License to Operate as a Small Business Investment Company

Notice is hereby given that an application has been filed with the Small Business Administration (SBA) pursuant to section 107.102 of the Regulations governing SBIC's (13 CFR 107.102 (1984)) under the name of Sea Gate Small Business Investment Company, Suite 1403, 245 Summit St., Toledo, Ohio 43603 for a license to operate in the Ohio area as a Corporation under the provisions of the Small Business Investment Act of 1958 (Act), as amended (15 U.S.C. 661 *et seq.*).

The Applicant will begin operations with private capital of \$1,010,000.

The officers, directors and shareholder of the Applicant are as follows:

George W. Haigh, 4206 Bonnie Brae Circle, Toledo, Ohio 43406—Chairman of the Board of Directors
Edwin M. Bergmark, 4544 Crossfields Rd., Toledo, Ohio 43623—President
Donald E. Breese, 3033 Dorian Drive, Toledo, Ohio 43614—Senior Vice President, General Manager
David A. Snively, 4908 Courville Rd., Toledo, Ohio 43623—Secretary
Richard E. Cautman, 5712 Firethorn, Toledo, Ohio 43615—Treasurer
Chester Devenow, 3000 Valleyview Drive, Toledo, Ohio 43615—Director
Edwin D. Dodd, 29620 Gleneagles Road, Perrysburg, Ohio 43251—Director
Avery C. Hand, Jr., 1130 By-the-Shore, Huron, Ohio 44839—Director
Robert J. Lowgan, 6206 Valley Park Drive, Toledo, Ohio 43623—Director
Duane Stranahan, Jr., 26281 West River Road, Perrysburg, Ohio 43551—Director
H.L. Thompson, 29953 Sussex Road, Perrysburg, Ohio 43551—Director
Robert G. Wingerter, 29800 Sussex Road, Perrysburg, Ohio 43551—Director
Toledo Trustcorp, Inc., Three SeaGate, Toledo, Ohio 43603—Sole Shareholder

Matters involved in SBA's consideration of the application include the general business reputation and character of the proposed owners and management, and the probability of successful operations of the company under their management, including adequate profitability and financial soundness, in accordance with the Small Business Investment Act of 1958, as amended, and the SBA Rules and Regulations.

Notice is further given that any person may, not later than 30 days from the date of publication of this Notice, submit written comments on the proposed Applicant. Any such communication should be addressed to the Deputy Associate Administrator for Investment, Small Business Administration, 1441 "L" St., NW., Washington, D.C. 20416.

A copy of this notice shall be published in a newspaper of general circulation in Toledo, Ohio

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: April 10, 1985.

Robert G. Lineberry,

Deputy Associate Administrator for Investment.

[FR Doc. 85-9169 Filed 4-16-85; 8:45 am]

BILLING CODE 8025-01-M

DEPARTMENT OF STATE

(CM-8/8411)

Reform Observation Panel for UNESCO: Closed Meeting

The Reform Observation Panel for UNESCO will meet on May 1, 1985 in Room 6323 of the Department of State, 21st and C Streets, N.W. Washington, D.C. The meeting will begin at 10:00 a.m.

- The principal agenda items will be:
- Briefing from Assistant Secretary of State Gregory J. Newell;
 - Reports from Panel members who have held consultations;
 - UNESCO's Executive Board Temporary Committee meeting, April 17-22; and
 - The Executive Board meeting May 6-June 21.

The purpose of the meeting will be to discuss UNESCO reform progress, means to encourage reform in UNESCO, and U.S. policy towards UNESCO. A classified briefing by Department of State officials and discussion of classified documents pursuant to Executive Order 12356 requires that the meeting be closed to the public pursuant to section 10(d) of the Federal Advisory Committee Act and 5 U.S.C. 552b (c)(1) and (c)(9)(B).

Requests for further information on the meeting should be directed to the Panel's Assistant Executive Secretary: Ms. D. Jamie Miller, Room 4334A, Department of State, 21st and C Streets, N.W., Washington, D.C. 20520 (202) 632-1534.

Dated: April 4, 1985.

Jean C. Berguast,
Executive Secretary, Reform Observation Panel.

[FR Doc. 85-9123 Filed 4-16-85; 8:45 am]

BILLING CODE 4710-10-M

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

(Docket No. 301-11)

Florida Citrus Commission et al.;
Hearing on Proposed
Recommendation

The Office of the United States Trade Representative (USTR) has scheduled a public hearing pursuant to Sec. 304(b)(1) of the Trade Act of 1974, as amended (19 U.S.C. 2414(b)(1)) for May 10, 1985 at 10:00 a.m. in Room 403, 600 17th Street, N.W., Washington, D.C. 20506. The purpose of the hearing is to invite public comment concerning the substance of the recommendation which USTR is required to make under Sec. 304(a) of the Trade Act of 1974 regarding its

investigation of preferential tariff treatment granted by the European Economic Community (EC) on certain citrus imports.

On November 12, 1976 USTR initiated an investigation under Sec. 301 on the basis of petitions filed by the Florida Citrus Commission, the California-Arizona Citrus League, the Texas Citrus Mutual and the Texas Citrus Exchange. The petitions alleged that the EC grants preferential tariff on imports on a wide range of citrus products when imported from certain Mediterranean countries and that these preferences have an adverse effect on U.S. citrus exports to the EC. The U.S. and EC were unable to resolve the issue through consultations held pursuant to the procedures of the General Agreement on Tariffs and Trade (GATT); therefore, the U.S. requested the GATT to establish a dispute settlement panel to review the U.S. complaint. The panel found that the EC preferences nullified and impaired U.S. benefits under GATT with respect to U.S. exports of oranges and lemons and recommended that the EC reduce the most-favored-nation tariff rate on these items. The panel's findings and recommendation were considered by the GATT Council on March 12 but no action was taken. They will be discussed again at the next meeting on April 30.

Under Sec. 304(a)(1), USTR, on the basis of its investigation, its consultations with the EC, and the GATT dispute settlement procedure, must recommend what action, if any, the President should take under Sec. 301 with respect to the issues raised in the petition. Under Sec. 301 President is authorized to take all appropriate and feasible action within his power to enforce U.S. rights under a trade agreement or to obtain the elimination of an act, policy, or practice of a foreign government or instrumentality that denies U.S. benefits under a trade agreement or is unjustifiable, unreasonable or discriminatory and a burden or restriction on U.S. commerce.

Sec. 301(b) specifically authorizes the President, *inter alia*, to suspend or withdraw the benefits of trade agreement concessions and to impose duties or other import restrictions on the products of, and fees or restrictions on the services of, a foreign country for such time as he deems appropriate. Measures under Sec. 301 may be taken on a discriminatory or non-discriminatory basis at the discretion of the President.

The Section 301 Committee therefore invites public comment as to what, if any, action USTR should recommend to the President in this case.

In accordance with 15 CFR 2006.9, requests to present oral testimony should be submitted to the Chairman, Section 301 Committee, Office of the United States Trade Representative, 600 17th Street, N.W., Washington, D.C. 20506 no later than May 3, 1985. Written briefs accompanying oral testimony must be submitted no later than May 8, 1985 and must conform to the requirements of 15 CFR 2006.8. Those interested parties who do not wish to present oral testimony but nevertheless wish to present written views should submit written briefs in accordance with 15 CFR 2006.8 no later than May 10, 1985. Rebuttal briefs may be submitted in accordance with 15 CFR 2006.8(c) no later than May 20.

Jeanne S. Archibald,
Chairman, Section 301 Committee.
[FR Doc. 85-9351 Filed 4-16-85; 8:45 am]

BILLING CODE 3190-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

(Summary Notice No. PE-85-6)

Petition for Exemption; Summary of
Petitions Received, Dispositions of
Petitions Issued

AGENCY: Federal Aviation Administration (FAA) DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption (14 CFR Part 11), this notice contains a summary of certain petitions seeking relief from specified requirements of the Federal Aviation Regulations (14 CFR Ch. I), dispositions of certain petitions previously received and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATE: Comments on petitions received must identify the petition docket number involved and must be received on or before: May 7, 1985.

ADDRESS: Send comments on any petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rules Docket (AGC-204), Petition Docket No. —, 800

Independence Avenue, SW.,
Washington, D.C. 20591.

FOR FURTHER INFORMATION CONTACT:

The petition, any comments received and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the

Rules Docket (AGC-204), Room 9f6,
FAA Headquarters Building (FOB 10A),
800 Independence Avenue, SW.,
Washington, D.C. 20591; telephone (202)
426-3644.

This notice is published pursuant to
paragraph (c), (e), and (g) of § 11.27 of

Part II of the Federal Aviation
Regulations (14 CFR Part 11).

Issued in Washington, D.C., on April 10,
1985.

Richard C. Beitel,

*Acting Assistant Chief Counsel, Regulations
and Enforcement Division.*

PETITIONS FOR EXEMPTION

Docket No.	Petitioner	Regulations affected	Description of relief sought
24488	Midwest Aviation, Inc.	14 CFR 21.181	To allow petitioner to operate certain aircraft utilizing the provisions of a minimum equipment list.
20048	Chalk's International Airlines	14 CFR 135.75(a)	To allow petitioner to conduct day visual flight rules (VFR) operations in Grumman G-73 Mallard airplanes without having approved airborne radar equipment installed in the airplanes.
24449	St. Lucia Airways Ltd.	14 CFR 21.181	To allow petitioner to operate certain aircraft utilizing the provisions of a master minimum equipment list.
24075	Rinker Materials Corp.	14 CFR 21.181	To allow petitioner to operate Beech King Air 200 aircraft utilizing the provisions of a minimum equipment list.
24483	R & F 727, Inc.	14 CFR 21.181	To allow petitioner to operate B-727 aircraft utilizing the provisions of a minimum equipment list.
24431	Old Ben Coal Co.	14 CFR 21.181	To allow petitioner to operate certain aircraft utilizing the provisions of a minimum equipment list.
24480	New York State Dept.	14 CFR 21.181	To allow petitioner to operate King Air 200 aircraft utilizing the provisions of a minimum equipment list.
24488	Nakbosa Papers, Inc.	14 CFR 21.181	To allow petitioner to operate a DH-125 aircraft utilizing the provisions of a minimum equipment list.
24485	National Medical Enterprises	14 CFR 21.181	To allow petitioner to operate Falcon 10 and Falcon 50 aircraft utilizing the provisions of a minimum equipment list.
24482	MacLean-Food Co.	14 CFR 21.181	To allow petitioner to operate a Citation I aircraft utilizing the provisions of a minimum equipment list.
24492	Harrah's Hotels & Casinos	14 CFR 21.181	To allow petitioner to operate certain aircraft utilizing the provisions of a minimum equipment list.
24489	Hach Company	14 CFR 21.181	To allow petitioner to operate a Beech King Air 200 aircraft utilizing the provisions of a minimum equipment list.
24470	Farm & Home Savings Association	14 CFR 21.181	To allow petitioner to operate a Falcon 20 aircraft utilizing the provisions of a minimum equipment list.
23430	Douglas Aircraft Co.	14 CFR 61.57(c)	To extend the May 1 termination date of Exemption 3754. That exemption allows pilots to meet the pilot-in-command landing recency requirements by using a Phase I advanced simulator.
22665	Ogna Service Co.	14 CFR 21.181	To extend the June 30 termination date of Exemption 3800 and amend the exemption to add an aircraft. Exemption 3800 allows petitioner to operate certain aircraft utilizing the provisions of a minimum equipment list.
22645	Buckeye Cellulose Corp.	14 CFR 21.181	To extend the July 31, 1985, termination date of Exemption 3834. That exemption allows petitioner to operate a Cessna 500 aircraft utilizing the provisions of a minimum equipment list.
24474	B.F. Goodrich Co.	14 CFR 21.181	To allow petitioner to operate certain aircraft utilizing the provisions of a minimum equipment list.
24487	AT & T Resource Management	14 CFR 21.181	Do.
24490	United Technologies	14 CFR 21.181	Do.
24545	United States Parachute Association	14 CFR 91.47	To allow the petitioner to carry up to 40 passengers in its Douglas DC-3/C-47 aircraft during the 1985 United States National Skydiving Championships in Muskogee, Oklahoma during the period of June 20 through July 17, 1985.
24559	Fort Howard Paper Co.	14 CFR 21.181	To allow petitioner to operate certain aircraft utilizing the provisions of a minimum equipment list.
24555	Rich Products Corp.	14 CFR 21.181	Do.
24558	TRW, Inc.	14 CFR 21.181	Do.
24556	Modine Manufacturing Company	14 CFR 21.181	Do.
24557	W.W. Grainger, Inc., Doerr Electric Corp.	14 CFR 21.181	Do.
24560	ANR Pipeline Co.	14 CFR 21.181	Do.
24562	Briston-Myers Co.	14 CFR 21.181	Do.
24564	Champion Int'l Corp.	14 CFR 21.181	Do.
24561	Weis Markets, Inc.	14 CFR 21.181	Do.
22635	Sierra Academy of Aeronautics	14 CFR Appendix C of Part 63	Extension of Exemption 3564 to allow petitioner to continue to conduct a Federal Aviation Administration (FAA) test program for flight engineer applicants who do not possess at least a commercial pilot certificate with an instrument rating to reduce the required 5 hours of flight training in an airplane and by incorporating static ground training in airplanes, subject to certain conditions and limitations.
24037	Wackenhut Services Incorporated	14 CFR 61.151(b)	To allow Mr. James T. Riddle to apply for an airline transport pilot certificate (ATCP) with a rotorcraft category rating without meeting the, at least 1,200 hours of flight time within the preceding 8 years requirement.
24503	Eastern Airlines Incorporated	14 CFR 121.391(a)(3)	To allow petitioner to block-off 2 of the 252 passenger seats on its A300-B4 aircraft for nighttime operation and carry only 5 flight attendants.
21144	American Airlines Flight Academy	14 CFR 121.99 and 121.351(a)	To extend the June 30 termination date of Exemption 1332, as amended. That exemption allows petitioner to operate airplanes between Wilmington, NC, and St. Croix and St. Thomas, via Nassau, without maintaining two-way radio communications between each airplane and the dispatch office.
24573	The Clorox Company	14 CFR 21.181	To allow petitioner to operate certain aircraft utilizing the provisions of a minimum equipment list.
24587	U.S. Jet Aviation	14 CFR 135.261(b)	To permit petitioner to operate its aircraft in a hospital emergency medical evacuation service without complying with the duty time limitations.
24588	Horizon Air	14 CFR 121.371(a) and 121.375	To allow Braathens S.A.F.E. to perform maintenance on petitioner's Fokker F-28 Mark 1000 aircraft.
24526	Masco Flight Operations	14 CFR 21.181	To allow petitioner to operate certain aircraft utilizing the provisions of a minimum equipment list.
24534	World Airways, Inc.	14 CFR 121.391(a)(1)	To allow petitioner to block off 4 of the 354 seats and operate its Douglas DC-10 aircraft with 7 flight attendants when the 8th attendant cannot be made available without undue delay or flight cancellation.

PETITIONS FOR EXEMPTION—Continued

Docket No.	Petitioner	Regulations affected	Description of relief sought
24515	United Airlines	14 CFR 121.434(c)(1)	To allow a pilot initially qualifying or upgrading as a pilot in command to be observed either by an FAA inspector of a United Airlines FAA-designated pilot examiner.
24544	Imperial International Incorporated	14 CFR 135.261(b)	To allow petitioner to operate its helicopter in hospital emergency medical evacuation service without complying with the duty time limitations.
21774	Finnair	14 CFR Parts 21 and 91	To allow petitioner to operate a leased U.S.-registered DC-10-30 aircraft, N345HC, using a Federal Aviation Administration (FAA)-approved minimum equipment list in conjunction with an FAA-approved continuous airworthiness maintenance program.
22706	Bankair, Inc.	14 CFR 135.225(e)(1)	Amendment to Exemption 3553A to permit petitioner to operate from several additional military airports using takeoff visibility minimums which are less than 1 mile and equal to or greater than the landing minimums established for that airfield, subject to certain conditions and limitations. Exemption 3553A, as amended, allows petitioner's pilots to operate from Myrtle Beach Air Force Base and Beaufort Marine Corps Air Station using those visibility minimums.
24566	Penn Corp. Financial, Inc.	14 CFR 21.181	To allow petitioner to operate certain aircraft utilizing the provisions of a minimum equipment list.
24541	Boeing Commercial Airplane Company	14 CFR 91.45	To permit petitioner to conduct turbine powered transport category airplanes ferry flights with one engine inoperative.
24540	Union Camp Corporation	14 CFR 91.45	To permit petitioner to conduct Lockheed JetStar 731's (N47UC, N48UC, and N49UC) ferry flights with one engine inoperative.
24432	Susquehanna Airlines	14 CFR 135.175	To allow petitioner to operate DeHavilland Heron Aircraft without radar equipment.
23809	The Relative Workshop	14 CFR 105.43(a)	Extension of Exemption 4047 to allow petitioner and Strong Enterprises, Inc.'s respective employees, representatives, and other volunteer experimental parachute test jumpers under their direction and control to allow such persons to make tandem parachute jumps. The exemption also allows pilots in command of aircraft involved in these operations to allow such persons to make these jumps wearing a dual parachute pack having at least one main parachute and one approved auxiliary parachute packed in accordance with § 105.43(a), subject to certain conditions and limitations.
24469	Parks College of St. Louis University	14 CFR Part 141	To allow students enrolled in the Associate and Bachelor of Science Degree in the Professional Pilot Degree Program to graduate from the appropriate courses when they have been trained to a performance standard.
21792	Aerones de Mexico, S.A.	14 CFR 21.181	To extend the June 30 termination date of Exemption 3266, as amended, to allow petitioner to operate certain aircraft utilizing the provisions of a minimum equipment list.
24578	Skystar International Airways	14 CFR 91.303	To allow petitioner to operate four Stage 1 Boeing 707 aircraft obtained after January 1, 1985 in noncompliance with the operating noise limits until hush kits are installed.
23225	Hughes Helicopters, Inc.	14 CFR 93.113	To allow special VFR operations in the Los Angeles, CA, control zone.

DISPOSITIONS OF PETITIONS FOR EXEMPTION

Docket No.	Petitioner	Regulations affected	Description of relief sought disposition
24392	Royal Air Maroc	14 CFR 91.303	To allow petitioner to operate one Stage 1 Boeing 707-320 aircraft for back of service in noncompliance with the operating noise limits until June 30, 1985. <i>Denied 3/21/85.</i>
NM-15	Aircraft Technical Service, Inc.	CAR 4b. 722	To permit certification of a Convair Model 440 for operation up to a maximum altitude of 35,000 ft. MSL with cabin pressure limited to currently approved pressure differential. <i>Granted 3/19/85.</i>
24231	Rich Int'l Airways, Inc.	14 CFR 91.303	To exempt petitioner from the January 1, 1985, noise level compliance date. <i>Amended partial grant 3/14/85.</i>
24098	Alaska Helicopters Inc.	14 CFR 135.225(d) and 121.652(a)	To amend Exemption 4109 which allows petitioner to operate BV-234 helicopter, with a passenger seating configuration of more than 30 seats and a payload capacity of more than 7,500 pounds, under Part 135, subject to certain conditions and limitations. It would allow petitioner to comply with § 135.225(d) instead of § 121.652(a). <i>Partial grant 3/19/85.</i>
24200	MCI Communications Corp.	14 CFR 21.181	To allow petitioner to operate a Falcon 50 aircraft utilizing the provisions of a minimum equipment list. <i>Granted 3/19/85.</i>
22262	Regional Airline Association	14 CFR 135.261(b)	To extend the 2/28/85 termination date of Exemption 3535C. That exemption allows petitioners members to assign a flight crewmember for duty during flight time if that assignment provides for at least 8, rather than 10, consecutive hours of rest during the 24-hour period preceding the planned completion of the assignment. <i>Granted 2/27/85.</i>
18881	Int'l Aerobatic Club (ICB)	14 CFR 91.22(a)(1)	To extend the March 31, 1985, termination date of exemption 2689, as amended. It would allow members of the ICB to participate and practice in aerobatic competitions without meeting the fuel requirements for VFR flight. <i>Granted 2/20/85.</i>
24439	Aeronautics and Astronautics, Inc.	14 CFR 91.303	To allow petitioner to operate one Stage 1 Boeing 707 airplane to Miami International Airport for maintenance purposes. <i>Denied 3/1/85.</i>
24442	Southern Air Transport	14 CFR 91.303	To allow petitioner to operate up to three Stage 1 Boeing 707-320C aircraft until hush kits are installed but in no event, beyond September 30, 1985. <i>Partial grant 3/12/85.</i>
23298	Bell Helicopter Textron, Inc.	14 CFR 133.1 and 133.45	To extend the termination date of Exemption 3718 that allows petitioner to perform external-load operations to exercise the Dallas/Ft. Worth Metroplex Helicopter Emergency Lifesaver Plan which involves lifting personnel in a Bell Fugh safety net on various occasions and at different locations, subject to certain conditions and limitations. <i>Granted 3/29/85.</i>
23716	World Balloon Corp.	14 CFR 47.15(b)	To allow relief from the conventional registration identification as provided in that section, and to request a special registration of N-WORLD. <i>Denied 10/26/84.</i>
24347	Ports of Call Travel	14 CFR 91.303	To exempt petitioner from January 1, 1985, noise level compliance date. <i>Partial grant 3/27/85.</i>
23716	World Balloon Corp.	14 CFR 47.15(b)	To allow petitioner to obtain special registration marks "N-WORLD" instead of the normal "N" number for its new balloon. <i>Denied 10/26/84.</i>

DISPOSITIONS OF PETITIONS FOR EXEMPTION—Continued

Docket No.	Petitioner	Regulations affected	Description of relief sought disposition
24118	Int'l. Air Service Co., Ltd.	14 CFR 121.613	To allow petitioner to release an aircraft to a destination airport when that airport's terminal forecast predicts at or above minimum weather at estimated arrival time, but also contains conditional language predicting the possible occurrence of below minimum weather during that period. <i>Denied 3/27/85.</i>
24069	Arro-Gun	14 CFR 91.42	To allow petitioner to conduct commercial agricultural ultra low volume spraying operations in a Tierra II aircraft under an experimental certificate. <i>Denied 3/15/85.</i>
24142	General Electric Co.	14 CFR 21.181	To permit petitioner to operate four Canadair Challenger CL-600-2A12 airplanes, N372G, N373G, N374G, and N375G, using a Federal Aviation Administration (FAA)-approved minimum equipment list (MEL). <i>Granted 3/15/85.</i>
20894	Trans-Colorado Airlines, Inc.	14 CFR 135.181(a)(2)	To allow petitioner to operate over V95 between Balco Intersection and Trees Intersection and over V95/V421 between Powers Intersection and Zeans Intersection and allow an alternate means of compliance with the performance requirements and use of procedures for compliance with the en route limitations. <i>Granted 3/29/85.</i>
23800	Simulator Training, Inc.	14 CFR 61.63(d)(2)	To allow certain practical test maneuvers and procedures to be performed in petitioner's Lockheed Electra L-188 training device in lieu of nonvisual simulator. <i>Partial grant 4/2/85.</i>
17681	Kenmore Air Harbor, Inc.	14 CFR 135.203(a)(1)	To renew Exemption 2528, as amended, to permit petitioner to conduct operations at an altitude below 500 feet over water outside of controlled airspace, subject to certain conditions and limitations. <i>Granted 4/1/85.</i>
24283	American Flyers	14 CFR 1641.65	To allow petitioner to develop and administer certain written tests for sirmen certification. <i>Granted 3/18/85.</i>
24282	Commonwealth of Pennsylvania	14 CFR 21.181	To allow petitioner to operate PA Piper Navajo and King Air 1390 aircraft utilizing the provisions of minimum equipment lists. <i>Granted 3/15/85.</i>
24266	Precision Airlines	14 CFR 61.31 and 135.243	To allow the operation of Dornier 228-301 aircraft at a gross weight exceeding 12,500 pounds without the pilot holding a type rating. <i>Granted 3/18/85.</i>
23468	Arabian American Oil Company	14 CFR 21.181	To allow the operation of aircraft under Part 91 utilizing the provisions of a minimum equipment list. It would extend the March 31, 1985, termination date of Exemption 3720, as amended. <i>Granted 3/22/85.</i>
21266	Flight Management Company	14 CFR 91.169 and 91.181	To extend the January 31, 1985, termination date of Exemption 3294A. It would allow petitioner to continue to operate certain small civil aircraft under the provisions of §§ 91.183 and 91.215. <i>Denied 3/18/85.</i>
22147	Boeing Commercial Airplane Company	14 CFR 91.195(a)(1)	To renew Exemption 3661 to allow petitioner to conduct noise measurement tests, ground proximity warning system research and development, and certification flight tests at altitudes lower than 1,000 feet above the surface. <i>Granted 3/15/85.</i>
18718	FlightSafety Int'l.	14 CFR 61.58(c) and 61.76(d)(2)	To extend the March 31, 1985, termination date of Exemption 2738, as amended. That exemption allows petitioner's trainees to complete a 24-month pilot-in-command check and a Category II pilot authorization check in an FAA-approved flight simulator. <i>Granted 3/29/85.</i>
24218	Pan American World Airways, Inc.	14 CFR Appendix H of Part 121	Relief from the limits on the conduct of Phase IIA training and checking utilizing the Phase I simulator to 3½ years from the date such approval was received from the Federal Aviation Administration (FAA). <i>Partial grant 3/21/85.</i>
24219	Eastern Air Lines, Inc.	14 CFR Appendix H of Part 121	Relief from the limit on the conduct of Phase IIA training and checking utilizing a Phase I simulator to 3½ years from the date such approval was received from the Federal Aviation Administration (FAA). <i>Granted 3/21/85.</i>

[FR Doc. 85-9163 Filed 4-16-85; 8:45 am]

BILLING CODE 4910-13-M

Federal Highway Administration

[BMCS Notice No. 85-6]

Driver's Record of Duty Status

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of granting of exemption.

SUMMARY: Notice is hereby given that the FHWA has granted an exemption to Frito Lay, Inc., Dallas, Texas, from certain requirements of § 395.8, Driver's record of duty status, of the Federal Motor Carrier Safety Regulations (FMCSR) conditioned upon the use of an on-board computer system.

EFFECTIVE DATE: April 10, 1985.

FOR FURTHER INFORMATION CONTACT: Mr. Neill L. Thomas, Bureau of Motor Carrier Safety, (202) 755-1011; or Mr. Thomas P. Holian, Office of the Chief Counsel, (202) 426-0346, Federal Highway Administration, Department of

Transportation, 400 Seventh Street SW., Washington, D.C. 20590.

SUPPLEMENTARY INFORMATION: Frito-Lay, Inc. requested a waiver of certain DOT regulations found at 49 CFR 395.8 to permit the use of an on-board computer system that electronically records and monitors driver and equipment performance in lieu of recording the required hours of service information in the driver's own handwriting. An exemption has been issued to Frito-Lay, Inc., that permits the use of an on-board computer system which, on demand, displays the information pertaining to hours of service and driver's record of duty status required by the FMCSR.

Deviation from the following provisions of 49 CFR 395.8 has been authorized:

- (1) That portion of paragraph (a) that requires the driver to prepare a record of duty status while on duty or driving;
- (2) That portion of paragraph (a) that requires the driver's record of duty status be prepared in duplicate;
- (3) That portion of paragraph (f)(2) that requires all entries relating to the

driver's duty status be made in the driver's own handwriting;

(4) The precise grid form found in paragraph (g) is waived to permit the use of an electronically produced grid; and

(5) Those parts of paragraphs (c) and (h)(5) requiring a highway mile post or intersection designation where change of duty status does not occur at a city, town or village only during the current trip. This information must be shown by the use of a code and a code description on the electronically produced grid.

This exemption only applies to Frito-Lay, Inc. drivers operating company controlled truck-tractors in interstate or foreign commerce that are equipped with an on-board computer system capable of creating hours of service documentation.

A copy of the grant of exemption and "Description of On-board Computer System and Justification For Experimental Authorization Waiver of Portion of 49 CFR Part 395" are available for inspection in room 3404, Bureau of Motor Carrier Safety, 400

Seventh Street, SW., Washington, D.C. 20590.

(49 U.S.C. 3102; 49 CFR 1.48)

Issued on: April 11, 1985.

Kenneth L. Pierson,

Director, Bureau of Motor Carrier Safety.

[FR Doc. 85-8180 Filed 4-16-85; 8:45 am]

BILLING CODE 4910-22-M

[FHWA Docket No. 85-20]

Study of a Federal Weight-Distance Truck Tax; Opening of Docket

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of request for comments.

SUMMARY: Section 933 of the Deficit Reduction Act of 1984 directs the Department of Transportation (DOT), in consultation with the Department of Treasury, to conduct a study of weight-distance truck taxes. The purpose of this notice is to describe the scope of the study and to establish a public docket for receipt of information and comments related to areas of investigation.

DATE: Comments must be received on or before October 1, 1986.

ADDRESS: Submit written comments preferably in triplicate, to FHWA Docket Number 85-20, FHWA, Room 4205, HCC-10, 400 Seventh Street, SW., Washington, D.C. 20590. Any comments received will be available for examination at the above address between 7:45 a.m. and 4 p.m. ET, Monday through Friday, except legal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard.

FOR FURTHER INFORMATION CONTACT: Mr. James R. Link, Chief, Operations Analysis Branch, (202) 426-0570; or Mr. Michael J. Laska, Office of Chief Counsel, (202) 426-0761, Federal Highway Administration, 400 Seventh Street, SW., Washington, D.C. 20590. Office hours are from 7:45 a.m. to 4:15 p.m. ET, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Study Mandate

Section 933 of the Deficit Reduction Act of 1984 (Pub. L. 98-369, 98 Stat. 494) directs the DOT, in consultation with the Secretary of the Treasury to conduct a study of the feasibility and ability of weight-distance truck taxes to provide equity among highway users, to ease compliance costs, and improve administrative efficiency. Further, the study is to evaluate the evasion potential of such taxes and assess the benefits to interstate commerce of replacing all Federal truck taxes, except

the fuel taxes, with a weight-distance tax. A final report on this subject, together with recommendations the Secretary of Transportation may deem advisable, is to be submitted to Congress no later than October 1, 1987.

Background

Prior Federal analysis of a national weight-distance truck tax has, to a great extent, been limited to assessment of its equity implications. The most recent Federal examination of weight-distance truck taxes was contained in the study of *Alternatives to Tax on Use of Heavy Trucks* mandated in section 513(g) of the Surface Transportation Assistance Act (STAA) of 1982 (Pub. L. 97-424, 96 Stat. 2097). During the study period there was a need to address, legislatively, the immediate concerns of the motor carrier industry regarding the use tax rates; this precluded an indepth assessment of weight-distance truck taxes. However, the study did conclude that the principal highway cost variables of vehicle weight and mileage are not fully measured by the current highway tax structure.

In its present form, the tax structure attempts to collect for many types of variable highway costs with either fixed fees or taxes on products that are surrogates for highway use. Fair and efficient user charges require that collections be made for a variety of vehicle characteristics and uses as precisely as possible. In the long-term, a national weight-distance tax could improve equity among highway users by increasing the precision with which highway costs can be matched with user fees. The report noted that more information and analysis were needed to determine the feasibility of a federally administered weight-distance tax. Subsequently, Section 933 of the Deficit Reduction Act (DRA) of 1984 mandated further analysis of the issues. As a preliminary step to the study, Federal Highway Administration officials met with the National Motor Carrier Advisory Committee (NMCAC) in January to discuss the study effort. Among other concerns, the NMCAC identified the following areas as essential to a successful study:

- An analysis of the impact of a weight-distance tax on carriers by type, especially owner-operators;
- An evaluation of the effects of weight-distance taxes on commerce;
- An assessment of costs of recordkeeping to assure compliance; and
- The opportunity for public comment and public hearings on the study.

Study Scope

The purpose of this study is to determine the likely costs, savings or other impacts to the Government and taxpayers created by a Federal weight-distance tax.

In conducting the study, the Department of Transportation, in consultation with the Department of the Treasury proposes to collect and analyze information related to:

- Improvement to equity of using gross weight or axle weight by configuration type in combination with mileage as the basis for highway taxes;
- Assessment of optional weight-distance tax schedules, mileage/weight thresholds, and tax rates;
- Governmental data and recordkeeping necessary to determine taxpayer liability and maintain compliance;
- The availability of taxpayer data to support tax payment;
- Administrative procedures necessary to collect and enforce the tax;
- Administrative costs, both government and private, of a weight-distance tax program;
- Identification and assessment of impacts on motor carriers, shippers, and commerce;
- Evasion potential and methods of mitigation; and
- The potential for State participation in the collection and/or enforcement of the tax.

To conduct this investigation, the following tasks are proposed:

- (1) Design conceptual weight-distance tax options to replace all Federal highway taxes, except fuel, and develop tax rates to meet highway cost responsibility assignments for 1990.
- (2) Compare options to identify and remove from consideration tax options that are seriously deficient based on likely administrative feasibility, taxpayer compliance, burdens on industry and equity criteria.
- (3) Develop detailed weight-distance tax options to include alternative administrative plans under two possible scenarios: a federally administered plan and a cooperative Federal-State plan where collection and enforcement responsibilities would be shared.
- (4) Evaluate the impact of options on carriers and shippers to include, but not be limited to: a taxpayer compliance burden; change in transportation costs affecting modal choice and product costs; and affects on equipment usage.
- (5) Assess the feasibility and efficiency of collection and enforcement procedures, evasion potential, equity improvements, and benefits to

commerce of optional administrative plans.

In addition, this Notice solicits comments and information on the following:

- Motor carrier administrative, recordkeeping and compliance experiences with States that impose weight-distance taxes including the amount and effects of administrative costs and tax payments on their operations and equipment usage and to the extent possible, comparison of the experience with those of other types of taxes; and

- State administrative (collection and enforcement) practices involving weight-distance taxes including administrative cost, evasion potential and methods of mitigation. Analyses conducted on modal diversion and economic impacts of State weight-distance taxes are also requested.

Those wishing to comment on any aspect of the study or provide information related to the subject of weight-distance truck taxes are requested to send them to the docket established by this Notice. Further, public comment will be solicited at public hearings during the course of this study. Details of such hearings will appear in later Notices.

Issued on April 5, 1985.

R. A. Barnhart,

Federal Highway Administrator, Federal Highway Administration.

[FR Doc. 85-9289 Filed 4-16-85; 8:45 am]

BILLING CODE 4910-22-M

DEPARTMENT OF THE TREASURY

Customs Service

(T.D. 85-70)

Fees Relating to Vessel Services, Container Stations, and Warehouses

AGENCY: U.S. Customs Service, Treasury.

ACTION: Notice of Revised Fee Schedules.

SUMMARY: To return to the Government the approximate costs of certain services provided to private interests by Customs officers, this document sets forth revised fees to be collected for the following services:

1. To perform vessel services;
2. To establish container stations; and
3. To establish, alter, and relocate a warehouse facility.

The fees are being adjusted to reflect the Federal pay increase, administrative overhead charge and Medicare. The fees shall remain in effect until revised.

EFFECTIVE DATE: April 17, 1985.

FOR FURTHER INFORMATION CONTACT:

James Kenny, Accounting Division, (202-566-2021),

and
John Holl, Office of Inspection and Control, (202-566-8151), Customs Headquarters, 1301 Constitution Avenue, NW., Washington, D.C. 20229.

SUPPLEMENTARY INFORMATION:

Background—Fees To Perform Vessel Services

Pub. L. 95-410, the "Customs Procedural Reform and Simplification Act of 1978," approved October 3, 1978, (the "Act"), repealed sections 2654, 4381, 4382, and 4383 of the Revised Statutes of the United States (19 U.S.C. 58; 46 U.S.C. 329, 330 and 333), the statutory authority under which Customs had been charging and collecting fees for specific services provided to vessels by Customs officers.

Because these "Navigation Fees," which are set forth in § 4.98(a), Customs Regulations (19 CFR 4.98(a)), did not cover the costs of providing the services, Section 214 of the Act authorized the Secretary of the Treasury to establish a new schedule of fees to be charged and collected for furnishing these services. The fees are to be consistent with 31 U.S.C. 9701, which provides that the costs of specific services for private interests shall be reimbursed to the Government.

By T.D. 80-25, published in the Federal Register on January 18, 1980 (45 FR 3570), Customs established a fee schedule to be used for 1980, and amended § 4.98(a), Customs Regulations, to provide that a revised fee schedule would be published in the Federal Register and Customs Bulletin in December of each year setting forth navigation fees for the specified vessel services to be performed during the following year. The revised fee schedule is to reflect not only changes in the rate of compensation paid to the Customs officer performing the service, but also a 15 percent administrative overhead charge on the cost to Customs of providing the service, (see T.D. 84-231, published in the Federal Register on November 23, 1984 (49 FR 46118)), and the Medicare compensation costs equal to 1.35 percent of the cost to Customs of providing the service (see T.D. 84-147, published in the Federal Register on July 16, 1984 (49 FR 26700)). The fees are to be calculated in accordance with § 24.17(d), Customs Regulations (19 CFR 24.17(d)), and based upon the amount of time the average service requires of a Customs officer in the fifth step of GS-9.

In a separate regulatory initiative, by T.D. 84-149, published in the Federal Register on July 16, 1984 (49 FR 28695), Customs amended § 4.98(a) to remove the requirement that the revised fee schedule be published in December of each year. That requirement was too restrictive, especially since there was no Federal pay increase in October 1983. As amended, § 4.98(a) provides that a revised fee schedule will be published "periodically" and will remain in effect until changed. That is consistent with the procedure followed in the publication of a fee charged to establish a container station in accordance with T.D. 83-56 (48 FR 9853, March 9, 1983), and discussed below.

Because of the latest Federal pay increase effective January 6, 1985, as well as the current rates for the administrative overhead charge and Medicare that Customs may assess on the services it provides, it is necessary for Customs to revise the schedule of fees to take into account this increased cost. The adjusted hourly rate used is \$18.15. The fees have been rounded off.

Action

The following revised schedule of navigation fees will remain in effect until revised:

Fee No. and description of services	Fee
1. Entry of vessel, including American, from foreign port:	
(a) Less than 100 net tons	\$9.00
(b) 100 net tons and over	18.00
2. Clearance of vessel, including American to foreign port:	
(a) Less than 100 tons	9.00
(b) 100 net tons and over	18.00
3. Issuing permit to foreign vessel to proceed from district to district, and receiving manifest	18.00
4. Receiving manifest of foreign vessel on arrival from another district, and granting a permit to unlade	18.00
5. Receiving post entry	9.00
6. Reserved	
7. Certifying payment of tonnage tax for foreign vessels only	4.50
8. Furnishing copy of official document, including certified outward foreign manifest, and others not elsewhere enumerated	18.00

Fee To Establish Container Stations

Container stations are secured areas within the U.S. into which containers of imported merchandise may be moved for the purpose of opening the container and delivering the contents before an entry is filed with Customs or duty is paid. A container station serves as a central location at a port for processing containerized merchandise which otherwise could not be handled timely at the dock, wharf, pier, or bonded carrier's terminal.

Sections 19.40 through 19.49, Customs Regulations (19 CFR 19.40-19.49), set forth the procedure for the establishment and use of container stations. To establish a container station under § 19.40, Customs Regulations, an application must be filed with the district director. Before the application may be approved, Customs must: (1) Determine that the application is in proper form; (2) survey the premises to determine that all physical requirements are met; (3) perform a background investigation of the applicant and the applicant's officers and employees; (4) prepare a report of that investigation; and (5) review the application, survey, and background investigation report, and prepare a response to the applicant.

Consistent with the User Charges Statute (31 U.S.C. 9701), by T.D. 83-56, published in the *Federal Register* on March 9, 1983 (48 FR 9853), Customs amended § 19.40, Customs Regulations, to authorize implementation of a fee schedule to establish a container station. That document provided that the fee schedule is to be published in the *Federal Register* and Customs Bulletin periodically to revise the fee to reflect the increased costs to establish the container station. The fee is to be calculated in accordance with § 24.17(d), Customs Regulations (19 CFR 24.17(d)). The published revised fee schedule will remain in effect until revised.

The fee charged for the service is based upon the amount of time the service requires of each Customs officer and equals the sum of the individual charges plus a charge for mileage incurred by the applicable Customs officer in using a vehicle to visit the premises to perform his or her respective task. The average mileage associated with performing the necessary tasks is 60 miles. Currently, mileage costs are reimbursed at 20.5 cents per mile. The mileage fee is \$12.30 (60 miles × 20.5 cents). As set out in T.D. 84-45, published in the *Federal Register* on February 21, 1984 (49 FR 6433), the current fee to establish a container station is \$879.00 (\$867.19 + 12.30, rounded off). The current rates of 15 percent for the administrative overhead charge and 1.35 percent for Medicare are figured into the revised fees as well.

The (1) grade and step of each Customs officer performing his or her respective service; (2) the adjusted hourly rate or pay utilized; (3) the individual charge of each respective service based on the hourly rate of pay of each Customs officer performing his or her respective service; and (4) the

total fee, including mileage, for the service rendered, follow:

Customs officer, grade/step	Individual charge
1. Clerk, 5/5	\$59.87
2. Inspector, 11/5	307.55
3. Agent, 12/5	579.07
4. Administrator, 13/5	62.61
Total	\$1,009.10

NOTE.—The mileage fee is \$12.30 (60 miles × 20.5 cents).

Action

The total fee to establish a container station is \$1,021.00 (\$1,009.10 + 12.30, rounded off). The fee will remain in effect until revised.

Fee to Establish, Alter, and Relocate a Warehouse Facility

By T.D. 82-204, published in the *Federal Register* on November 1, 1982 (47 FR 49355), Customs amended various parts of the Customs Regulations to implement changes relating to the control of merchandise in Customs bonded warehouses by establishing an audit-inspection program. A Customs bonded warehouse is a building or other secured area in which dutiable goods may be stored, manipulated, or undergo manufacturing operations without payment of duty.

As amended by T.D. 82-204, § 19.5, Customs Regulations (19 CFR 19.5), provides that each warehouse proprietor will be charged a fee to establish, alter, or relocate a warehouse facility which shall be determined under 31 U.S.C. 9701. Each warehouse proprietor granted the right to operate a warehouse facility shall be charged an annual fee which shall be determined under section 555, Tariff Act of 1930, as amended, (19 U.S.C. 1555). The fees will be revised annually and published in the *Federal Register* and Customs Bulletin.

The purpose of the annual warehouse fee is to reimburse the Customs appropriation for services rendered to the warehouse community including audit, inspection, and related administrative costs, and is to be projected on the basis of the actual annual cost to Customs in the preceding year plus any Federal salary increases. The current rates for the administrative overhead charge and Medicare are figured into the fees as well. By T.D. 85-36 published in the *Federal Register* on February 27, 1985 (50 FR 8043) the annual fee was increased from \$850.00 to \$1400.00. Any increases in that fee will be subject to another Federal Register document. As set out in T.D. 84-45, published in the *Federal Register* on February 21, 1984 (49 FR 6433), the current fee to establish a bonded

warehouse is \$879.00; the current fee to alter or relocate an existing bonding warehouse is \$328.00.

To recover the increased costs to Customs, the fees are to be calculated in accordance with § 24.17(d), Customs Regulations.

Action

The following fee schedule to establish, alter, and relocate a warehouse facility will remain in effect until revised.

1. Establish a Bonded Warehouse—\$1,021.00.

2. Alter an Existing Bonded Warehouse—\$442.00.

3. Relocate an Existing Bonded Warehouse—\$442.00.

The fees have been rounded off to the nearest dollar.

Authority

(R.S. 251, as amended (19 U.S.C. 66), section 312, 46 Stat. 692, as amended (19 U.S.C. 1312), section 551, 46 Stat. 742, as amended (19 U.S.C. 1551), section 555, 46 Stat. 743, as amended (19 U.S.C. 1555), section 624, 46 Stat. 759 (19 U.S.C. 1624), section 22, 67 Stat. 520 (19 U.S.C. 1646a), 92 Stat. 888 (Pub. L. 95-410), 96 Stat. 1051 (31 U.S.C. 9701))

Drafting Information

The principal author of this document was Glen E. Vereb, Regulations Control Branch, Office of Regulations and Rulings, Customs Headquarters. However, personnel from other Customs offices participated in its development.

Alfred R. De Angelus,

Acting Commissioner of Customs.

Approved: March 29, 1985.

John M. Walker, Jr.,

Assistant Secretary of the Treasury.

[FR Doc. 85-9214 Filed 4-16-85; 8:45 am]

BILLING CODE 4820-02-M

Removal of Prohibition on the Importation of Tuna and Tuna Products From the Solomon Islands

AGENCY: U.S. Customs Service, Treasury.

ACTION: General notice.

SUMMARY: This notice is to advise that under the Fishery Conservation and Management Act of 1976 ("the Act"), the Assistant Secretary of State for Oceans and International Environmental and Scientific Affairs has notified the Secretary of the Treasury that the reasons for the imposition of a prohibition on the importation of tuna and tuna products from the Solomon Islands no longer prevail. Accordingly, the prohibition against the entry for consumption or withdrawal from

warehouse for consumption of tuna and tuna products from the Solomon Islands is removed.

EFFECTIVE DATE: The prohibition against the entry for consumption or withdrawal from warehouse for consumption of tuna and tuna products from the Solomon Islands is removed effective April 17, 1985.

FOR FURTHER INFORMATION CONTACT: Harrison C. Feese, Entry, Operations and Trade Control Branch, Office of Commercial Operations, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, D.C. 20229 (202-566-8651).

SUPPLEMENTARY INFORMATION:

Background

Section 205(a)(4)(C) of the Fishery Conservation and Management Act of 1976 (16 U.S.C. 1801, *et seq.*), provides that the Secretary of State shall certify to the Secretary of the Treasury any determination that a fishing vessel of the U.S., while fishing in waters beyond any foreign nation's territorial sea, to the extent that such sea is recognized by the U.S., has been seized by a foreign nation as a consequence of a claim of jurisdiction not recognized by the U.S. The responsibility for this certification was delegated to the Assistant Secretary of State for Oceans and International Environmental and Scientific Affairs by Department of State Delegation of Authority No. 138 of April 29, 1977.

Pursuant to section 205(b) of the Act, upon receiving the certification, the Secretary of the Treasury is required to take such action as may be necessary and appropriate to prohibit the importation of all fish and fish products from the fishery involved.

Section 205(c) of the Act provides that if the Secretary of State finds that the reasons for the import prohibition no longer prevail, the Secretary of State shall notify the Secretary of the Treasury, who shall promptly remove the import prohibition.

On August 23, 1984, a notice was published in the Federal Register (49 FR 33526) advising that under section 205(a)(4)(C) of the Act, on July 31, 1984, the Assistant Secretary of State for Oceans and International Environmental and Scientific Affairs certified to the Secretary of the Treasury that a U.S. fishing vessel, while fishing

in waters beyond any foreign nation's territorial sea, to the extent that such sea is recognized by the U.S., was seized by the Solomon Islands as a consequence of a claim of jurisdiction which is not recognized by the U.S. Under the authority of section 205 (b) and (c) of the Act, on August 9, 1984, the Secretary of the Treasury determined that the entry for consumption or withdrawal from warehouse for consumption of tuna and tuna products from the Solomon Islands was prohibited until the Department of State notified the Secretary of the Treasury that the reasons for this prohibition no longer prevailed.

On March 6, 1985, the Assistant Secretary of State for Oceans and International Environmental and Scientific Affairs informed the Secretary of the Treasury that the reasons for the imposition of the import prohibition on tuna and tuna products no longer prevail. Accordingly, the prohibition against the entry for consumption or withdrawal from warehouse for consumption of tuna and tuna products from the Solomon Islands is removed.

Drafting Information

The principal author of this document was Glen E. Vereb, Regulations Control Branch, Office of Regulations and Rulings, Customs Headquarters. However, other personnel in the Customs Service and the Treasury Department participated in its development.

Dated April 2, 1985.

John M. Walker, Jr.,

Assistant Secretary of the Treasury.

[FR Doc. 85-9213 Filed 4-16-85; 8:45 am]

BILLING CODE 4820-02-M

UNITED STATES INFORMATION AGENCY

Grants Program: Accredited U.S. Institution of Higher Education in Support of an Undergraduate Scholarship Program for Central American Students

Reference: OMB clearance number 3116-0179. Expiration date January 31, 1987.

The Bureau of Education and Cultural Affairs announces a program of United

States government-sponsored undergraduate scholarships for Central Americans to study at accredited U.S. institutions of higher education. The program has the following broad objectives: to improve the range and quality of educational opportunities for young Central Americans of limited financial means; to match educational opportunities with skill shortages in Central America; to build lasting links between the U.S. and Central America. Student scholarship awards funded by USIA through pilot-project grants to U.S. institutions of higher education may range from twelve to thirty months in length, including English language training and other program enhancements. An education institution may apply for only one program per campus. No one campus will receive fewer than five nor more than fifteen students, to be identified by a separate, Agency-sponsored mechanism.

To achieve the program's goals, two broad project types have been identified: undergraduate programs for primary and secondary school teachers, to upgrade knowledge of selected disciplines and to improve teaching skills; and undergraduate advanced programs in several subject disciplines.

Current plans call for recruiting students from Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and Panama in subject fields of the following disciplines: education, social sciences, natural sciences, business, management, engineering, health.

Exact program requirements and dates will be specified in a Request for Proposals (RFP) to be issued on or about May 15, 1985.

To receive a copy of the RFP and supporting materials, interested academic institutions should write to: Office of Academic Programs, Bureau of Educational and Cultural Affairs, United States Information Agency, Washington, D.C. 20547, Attention: Dr. Alan Adelman, Telephone: (202) 485-7365.

Dated: April 10, 1985.

Ronald L. Trowbridge,

Associate Director, Bureau of Educational and Cultural Affairs.

[FR Doc. 85-9245 Filed 4-16-85; 8:45 am]

BILLING CODE 8230-01-M

Sunshine Act Meetings

Federal Register

Vol. 50, No. 74

Wednesday, April 17, 1985

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

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1

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

TIME AND DATE: 10:00 a.m., Monday, April 22, 1985.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Proposed amendment to Regulation AA (Unfair or Deceptive Acts or Practices) to implement, as to banks, the Credit Practices Rule adopted by Federal Trade Commission. (Proposed earlier for public comment; Docket No. R-0006)

2. Any items carried forward from a previously announced meeting.

Note. This meeting will be recorded for the benefit of those unable to attend. Cassettes will be available for listening in the Board's Freedom of Information Office, and copies may be ordered for \$5 per cassette by calling (202) 452-3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, D.C. 20551.

CONTACT PERSON FOR MORE INFORMATION:

Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204.

Dated: April 12, 1985.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 85-9315 Filed 4-15-85; 3:11 pm]

BILLING CODE 6210-01-M

2

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

TIME AND DATE: Approximately 10:45 a.m., Monday, April 22, 1985, following a recess at the conclusion of the open meeting.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street

entrance between 20th and 21st Street, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Proposed purchase of computers within the Federal Reserve System.

2. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System Employees.

3. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION:

Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: April 12, 1985

James McAfee,

Associate Secretary of the Board.

[FR Doc. 85-9316 Filed 4-15-85; 12:00 pm]

BILLING CODE 6210-01-M

3

NUCLEAR REGULATORY COMMISSION

DATE: Weeks of April 15, 22, 29, and May 6, 1985.

PLACE: Commissioners' Conference Room, 1717 H Street, N.W., Washington, D.C.

STATUS: Open and Closed.

MATTERS TO BE CONSIDERED:

Week of April 15

Wednesday, April 17

2:30 p.m.

Briefing on TMI-1 Steam Generator and Other Plant Matters (Public Meeting)

Thursday, April 18

9:30 a.m.

Responses to NRC Staff Comments on TMI-1 Steam Generators (Public Meeting)

11:15 a.m.

Affirmation/Discussion and Vote (Public Meeting)
a. Indian Point Order (tentative)

Week of April 22—Tentative

Tuesday, April 23

9:30 a.m.

Discussion of Pending Investigations (Closed—Ex. 5 & 7)

11:00 a.m.

Discussion of Diablo Canyon-2 Contested Issues (Closed—Ex. 10) (tentative)

2:30 p.m.

Discussion/Possible Vote on Diablo Canyon-2 Low Power License (Public Meeting)

Thursday, April 25

2:00 p.m.

Affirmation Meeting (Public Meeting) (if needed)

Week of April 29—Tentative

Wednesday, May 1

10:00 a.m.

Discussion of Low Level Waste Issues (Public Meeting)

2:00 p.m.

Periodic Briefing on NTOLs (Open/Portion may be Closed—Ex. 5 & 7)

4:00 p.m.

Affirmation Meeting (Public Meeting) (if needed)

Thursday, May 2

10:00 a.m.

Discussion of Modified Rule on Material False Statements (Public Meeting)

Week of May 6—Tentative

Wednesday, May 8

10:30 a.m.

Briefing by AIF on State of the Industry (Public Meeting)

Thursday, May 9

10:00 a.m.

Briefing on Brookhaven Report on Independent Safety Organization (Public Meeting)

2:00 p.m.

Executive Branch Briefing (Closed—Ex. 1)

3:30 p.m.

Affirmation Meeting (Public Meeting) (if needed)

Friday, May 10

2:00 p.m.

Periodic Meeting with Advisory Committee on Reactor Safeguards (Public Meeting)

TO VERIFY THE STATUS OF MEETINGS CALL (RECORDING): (202) 634-1498.

CONTACT PERSON FOR MORE INFORMATION:

Julia Corrado (202) 634-1410.

Julia Corrado,

Office of the Secretary.

April 12, 1985.

[FR Doc. 85-9381 Filed 4-15-85; 4:30 pm]

BILLING CODE 7590-01-M

4

PACIFIC NORTHWEST ELECTRIC POWER AND CONSERVATION PLANNING COUNCIL
STATUS: Open.

TIME AND DATE: April 24-25, 1985, 9:00 a.m.

PLACE: Federal Building, South Auditorium, 915 Second Avenue, Seattle, Washington.

MATTERS TO BE CONSIDERED:

- Council Decision on Draft Load Forecasts
- Staff Presentation on the Status of Resource Portfolio Analysis
- Staff Presentation on Institutional Arrangements Issue Paper
- Council Decision on Use of Non-Firm Power (Including the Interruptibility of the Direct Service Industries)
- Public Comment on Proposed Council Interim Access Policy Issue Paper
- Public Comment on Out-of-Region Imports/Exports Issue Paper
- Staff Presentation and Public Comment on Re-Evaluation of the Model Conservation Standards Issue Paper
- Staff Presentation on Potential and Achievable Conservation Issue Paper
- Council Decision on Cost and Availability of Generating Resources
- Staff Presentation on Lost Opportunity Resources
- Public Comment on Research, Development and Demonstration of Promising Resources
- Council Business

Public comment will follow each item.

FOR FURTHER INFORMATION CONTACT:

Ms. Bess Wong, (503) 222-5161.

Edward Sheets,

Executive Director.

[FR Doc. 85-9282 Filed 4-15-85; 8:45 am]

BILLING CODE 0000-00-M

5

SECURITIES AND EXCHANGE COMMISSION

Notice is hereby given pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94-409, that the Securities and Exchange Commission will hold the following meetings during the week of April 22, 1985.

An open meeting will be held on Tuesday, April, 23, 1985, at 2:30 p.m., in Room 1C30, followed by a closed meeting.

The Commissioners, Counsel to the Commissioners, the Secretary of the Commission, and recording secretaries will attend the closed meeting. Certain staff members who are responsible for the calendared matters may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, the items to be considered at the closed meeting may be considered pursuant to one or more of the exemptions set forth in 5 U.S.C. 552b(c) (4), (8), (9) (A) and (10) and 17 CFR 200.402(a)(4), (8), (9)(i) and (10).

Commissioner Cox, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matter of the open meeting scheduled for Tuesday, April 23, 1985, at 2:30 p.m., will be:

1. Consideration of whether to approve under section 210(b) of the Investment Advisers Act of 1940 a program to share information with state securities officials regarding Commission adviser examinations. For further information, please contact Gene A. Gohlke at (202) 272-2024.

2. Consideration of whether to propose for public comment a revised Form ADV under the Investment Advisers Act of 1940 which would make the investment adviser registration application form a uniform form for use by both the commission and the states. For further information, please contact Mary Podesta at (202) 272-2107.

3. Consideration of whether to issue a release proposing for public comment revisions to Form BD, other related technical changes, and amendments to the broker-dealer successor rules, to reduce the regulatory burden on broker-dealers by revising the disciplinary question to remove duplicative information requirements and narrow the scope of that question, by clarifying the information required to be disclosed on the schedules, by making the information requested under Rule 17a-3 of the Securities Exchange Act of 1934 conform to

that requiring in the revised Form U-4, and by amending the broker-dealer successor rules to allow a broker-dealer to file an amendment to Form BD rather than a complete Form BD. For further information, please contact Valerie Golden at (202) 272-2848.

4. Consideration of an amendment to Rule (b)(2) of the Commission's Conduct Regulation, 17 CFR 200.734-3(b)(2). For further information, please contact Myrna Siegel at (202) 272-2430.

5. Consideration of whether to adopt two new registration forms, Forms S-4 (for all registrants) and F-4 (for certain foreign private issuers) to be used for the registration of securities in connection with merger proxies and exchange Patricia B. Magee at (202) 272-2589 (re Form S-4) or Martin L. Meyrowitz at (202) 272-3250 (re Form F-4).

6. Consideration of whether to issue a release proposing technical amendments to Rule 3A-02 of Regulation S-X, "Consolidated financial statements of the registrant and its subsidiaries." For further information, please contact Dorothy Walker at (202) 272-7343.

(This item was previously noticed in 50 FR 14192, April 10, 1985)

The subject matter of the closed meeting scheduled for Tuesday, April 23, 1985, following the 2:30 p.m. open meeting, will be:

Formal orders of investigation.
Settlement of administrative proceedings of an enforcement nature.
Institution of administrative proceedings of an enforcement nature.
Institution of injunctive actions.
Opinion.

At times changes in commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Angela Hall at (202) 272-3085.

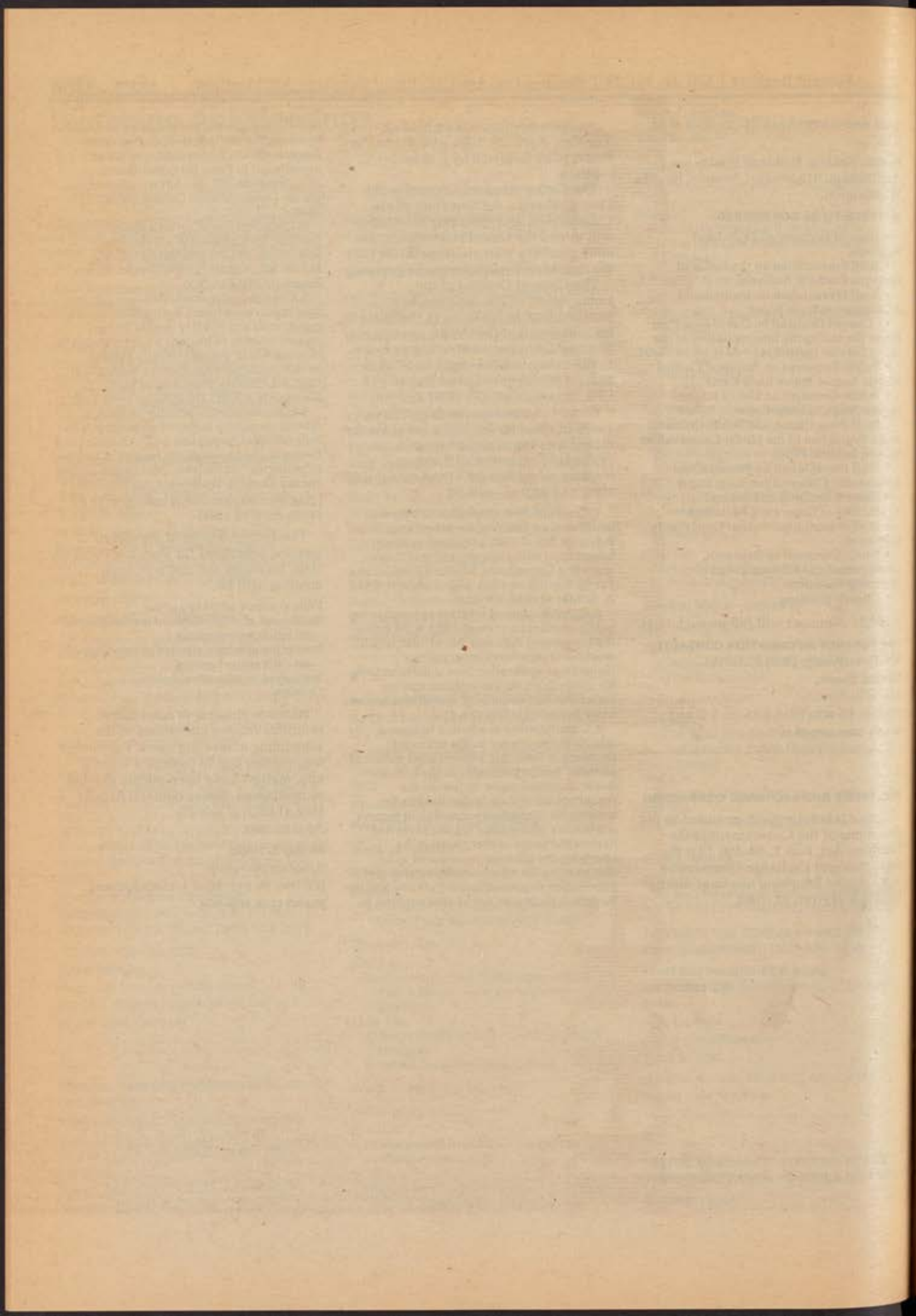
April 15, 1985.

Shirley E. Hollis,

Assistant Secretary.

[FR Doc. 85-9382 Filed 4-15-85 3:45 pm]

BILLING CODE 8010-10-M



Federal Register

**Wednesday
April 17, 1985**

Part II

Department of the Interior

Bureau of Indian Affairs

List of Indian Estates Affected by Old Age Assistance Claims; Notice

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

List of Indian Estates Affected by Old Age Assistance Claims

ACTION: Notice of Reimbursement.

This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Deputy Assistant Secretary—Indian Affairs by 209 DM 8.

SUMMARY: This notice lists all Indian trust estates identified by the Department of the Interior, from which unauthorized disbursements were made by the Secretary of the Interior to States, or political subdivisions thereof, as reimbursement for old age assistance provided to deceased Indians before death in violation of Federal laws. This notice is required by section 4(a) of the Old Age Assistance Claims Settlement Act of October 19, 1984, Pub. L. 98-500.

DATE: This notice establishes that tribes, bands, groups and individual Indians shall have until October 14, 1985, to submit to the Secretary of the Interior, through the proper Area Office, the names of any additional trust estates from which unauthorized disbursements were made and which are not contained in this list.

FOR FURTHER INFORMATION CONTACT:

Aberdeen Area Director, Bureau of Indian Affairs, 115 4th Avenue, S.E., Aberdeen, South Dakota 57401, Telephone: (605) 225-0250;

Albuquerque Area Director, Bureau of Indian Affairs, 5301 Central Avenue, N.E., P.O. Box 8327, Albuquerque, New Mexico 87198, Telephone: (505) 766-3170;

Anadarko Area Director, Bureau of Indian Affairs, Federal Building, P.O. Box 368, Anadarko, Oklahoma 73005, Telephone: (405) 247-6673;

Billings Area Director, Bureau of Indian Affairs, 316 North 26th Street, Billings, Montana 59101, Telephone: (406) 657-6315;

Eastern Area Director, Bureau of Indian Affairs, 1951 Constitution Avenue, N.W., Washington, D.C. 20245, Telephone: (703) 235-2571;

Juneau Area Director, Bureau of Indian Affairs, Federal Building, P.O. Box 3-8000, Juneau, Alaska 99802, Telephone: (907) 586-7177;

Minneapolis Area Director, Bureau of Indian Affairs, Chamber of Commerce Building, 15 South Fifth Street, 10th Floor, Minneapolis, Minnesota 55402, Telephone: (612) 349-3631;

Muskogee Area Director, Bureau of Indian Affairs, Old Federal Building, Muskogee, Oklahoma 74401, Telephone: (918) 687-2295;

Navajo Area Director, Bureau of Indian Affairs, P.O. Box M., Window Rock, Arizona 86515, Telephone: (602) 871-5151;

Phoenix Area Director, Bureau of Indian Affairs, 3030 North Central, P.O. Box 7007, Phoenix, Arizona 85011, Telephone: (602) 241-2305;

Portland Area Director, Bureau of Indian Affairs, 1425 Irving Street, N.E., Portland, Oregon 97208, Telephone: (503) 231-6702; and

Sacramento Area Director, Bureau of Indian Affairs, 2800 Cottage Way, Sacramento, California 95825, Telephone: (916) 484-4682.

SUPPLEMENTARY INFORMATION: The Old Age Assistance Claims Settlement Act, Pub. L. 98-500, authorizes and directs the Secretary of the Interior to pay entitled individuals their portions of any unauthorized disbursement made from the trust estate of a deceased Indian to a State, or a political subdivision thereof, as reimbursement for old age assistance provided to the deceased Indian before death in violation of Federal laws governing Indian trust property. The Secretary of the Interior is further directed to search the records of the Department of the Interior to identify individuals who are entitled to payment, and to ascertain the amount of the unauthorized disbursement to which each of the individuals would be entitled. Any payment under the Act shall include simple interest at a rate of five percent per annum from the date on which such unauthorized disbursement was made from the trust estate of the deceased Indian. No payments shall be made with respect to any unauthorized disbursement from the trust estate of a deceased Indian if the total amount of such unauthorized disbursement was less than \$50.

This notice lists all Indian trust estates, identified by the Department of the Interior, from which unauthorized disbursements were made for the purpose of reimbursement for old age assistance. Copies of the Old Age Assistance Claims Settlement Act, Pub. L. 98-500, and this document are being provided to all federally acknowledged Indian tribes.

Indian tribes, bands, groups and individual Indians have 180 days, or until October 14, 1985, to submit to the appropriate area Office, in writing, the names of any additional qualified estates not listed in this document. (See the **FOR FURTHER INFORMATION CONTACT** section of this document for the names, addresses and telephone numbers of the Area Offices.) The name of any additional qualified estate submitted to an Area Office must be accompanied

by: (1) The name and tribal affiliation of the Indian decedent, (2) the date and number of the Departmental probate order determining heirs of the trust estate, and (3) evidence that a payment was made from the trust estate of the decedent as reimbursement for old age assistance. Within 30 days after the expiration of the 180-day period, the Secretary of the Interior will publish in the *Federal Register* a supplemental list identifying those additional qualified estates submitted to Area Offices by tribes, bands, groups and individual Indians.

The payment and acceptance of any claim, after its determination in accordance with the Act, shall be a full discharge to the United States and any State, or political subdivision thereof, of all claims and demands touching any of the matters involved in the controversy.

Because of the numerous estates listed in the document, this notice may be subject to technical clarification or change.

John W. Fritz,

Deputy Assistant Secretary—Indian Affairs.

Instruction Sheet

Each estate from which an unauthorized payment was made has been assigned a nine or ten character issue number (a letter followed by eight or nine numbers). The first six characters identify a specific Bureau of Indian Affairs Area Office, Agency Office and tribe. The last three or four characters represent the specific numbers assigned to that estate from which an unauthorized payment was made. For example, A013400001 indicates:

A01—Aberdeen Area Office/Cheyenne River Agency

340—Cheyenne River Sioux Tribe

0001—Estate number one

To locate an estate, begin with the Table of Contents which lists each affected tribe (grouped by Area Office and Agency) and the pages where the estates for individuals affiliated with such tribe can be found. The list of estates has been reproduced by photographing two pages of the list to each *Federal Register* page. The page number referred to in the Table of Contents is located at the top center above the name of the Area Office and is not the five digit *Federal Register* page number located on the outer portion of each page.

If a tribe is not listed in the Table of Contents, no estate was identified for any individual affiliated with such tribe.

Each page of estates contains five columns of information under the

headings: Issue Number, Decedent Name, Decedent ID, \$ Allowed, \$ Paid.

Issue Number: The nine or ten character code (explained above) which identifies the Area Office/Agency/Tribe/and specific number assigned to that estate.

Decedent Name: The name of the deceased Indian whose Departmental records contain evidence that an unauthorized payment was made from his/her trust estate as reimbursement for old age assistance.

Decedent ID: The decedent's identification number. This number usually coincides with the decedent's allotment number, tribal enrollment number, or, in their absence, a number assigned by the Bureau of Indian Affairs.

\$ Allowed: The amount of money, cited in the decedent's probate order, which was allowed as a claim to be paid from the decedent's trust estate as

reimbursement to the State, or political subdivision thereof, for old age assistance. This figure appears in the list as an indication that the Departmental records contain evidence that some money was actually paid from the decedent's trust estate as reimbursement for old age assistance.

\$ Paid: The amount of money actually paid (the amount of the unauthorized disbursement) from the decedent's trust estate as reimbursement to the State, or political subdivision thereof, for old age assistance. This figure is supported by evidence appearing in Departmental records. Where the Departmental records contain evidence that money was paid from the decedent's trust estate as reimbursement for old age assistance, but the exact amount is not known, the word UNKNOWN appears in this column; further research is needed to ascertain such amount. Those amounts ascertained after this list is

published will appear on the supplementary list of estates to be published in the Federal Register 30 days after the expiration of the aforementioned 180-day period.

If, after locating an estate on the list, you desire further information, call or write the Area Office under which the estate is listed. The names, addresses, and telephone numbers for all Area Offices are contained in the **FOR FURTHER INFORMATION CONTACT** section of this document. Be sure to include the complete issue number in any correspondence with the Bureau of Indian Affairs Area or Agency Office. It is important to remember that additional qualified estates must be submitted in writing, together with evidence of the unauthorized disbursement, to the appropriate Area Office within 180 days of the publication of this document.

BILLING CODE 4310-02-M

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PAGE 1

ASCENDING AREA

TRIBE CODE	AGENCY	TRIBE NAME	PAGE	ISSUE NUMBER	NAME OF DECEDENT	DECEDENT ID	ALLOWED	#PAID
ARIZONA AREA								
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0004	JAMES ELLER (WILSON)	42	471.50	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0005	HANFAP L. NANCY (WEST)	38	671.50	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0006	THOMAS LOVEJOY	56	2,454.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0007	JOHN A. LOVEJOY	186137	454.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0008	MINNIE LAMANCE	0249	27.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0009	CIRCLE EAGLE WILLIAM (FOUR)	1408	3,743.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0010	LONE HORSE PETER	1610	630.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0011	YELLOW SHIELD KNIFE NELLIE	2114	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0012	TOP OF THE LODGE JESSIE (EAGLE)	2022	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0013	LITTLE CROW GEORGE	1944	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0014	LEAF WILHELM	1944	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0015	LITTLE WOUNDED JAMES	1441	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0016	LINDLEY LIZZIE N.	1244	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0017	WALKS RUNNING RATTLE CLARA	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0018	WHITE WOLF THOMAS	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0019	JAMES AFRID OF LIGHTENING	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0020	DOG AR. ABRAHAM	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0021	WAGSHALL THOMAS	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0022	RICH LOUISE MARCELLE	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0023	FIELDER TWO SPEARS ANNIE	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0024	FOX LOUISE (BRIGET CURLEY)	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0025	HAWK THAT DAVES SOLAMON	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0026	BLACK CHICKEN SAPHIA	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0027	RED HEAD NELLIE	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0028	SETS OFF IDA	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0029	BROWS AT A DISTANCE JESSIE	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0030	COUNTING MARY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0031	CHAMBER NELLIE	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0032	RED BIRD MARY ALICE	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0033	RUCHEAUX JENNIE	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0034	CONDON JOSEPHINE	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0035	MAFFERY BERT C.	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0036	MAFFERY JOSEPH (LITTLE HAWK)	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0037	TALIS GEORGE	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0038	FLAD DEAD EUGEN	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0039	FLAD DEAD EUGEN	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0040	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0041	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0042	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0043	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0044	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0045	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0046	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0047	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0048	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0049	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0050	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0051	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0052	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0053	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0054	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0055	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0056	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0057	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0058	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0059	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0060	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0061	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0062	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0063	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0064	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0065	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0066	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0067	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0068	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0069	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0070	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0071	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0072	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0073	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0074	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0075	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0076	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0077	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0078	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0079	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0080	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0081	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0082	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0083	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0084	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0085	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0086	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0087	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0088	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0089	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0090	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0091	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0092	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0093	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0094	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0095	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0096	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0097	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0098	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0099	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0100	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0101	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0102	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0103	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0104	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0105	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0106	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0107	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0108	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0109	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0110	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0111	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0112	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0113	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0114	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0115	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0116	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0117	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0118	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0119	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0120	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0121	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0122	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0123	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0124	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0125	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0126	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0127	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0128	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0129	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0130	BALL CLAY	1236	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0131	BALL CLAY</			

ABERDEEN AREA

ISSUE NUMBER	NAME OF DECEDENT	DECEDENT ID	ALLOWED	PAID
AO1-00151	POOR ELK ANNIE	1322	1.50	1.50
AO1-00152	FOX THOMAS	3080	1.50	1.50
AO1-00153	LEE HENRY	401	1.50	1.50
AO1-00154	ALICE EDWARD	85	1.50	1.50
AO1-00155	MARKSALL IIA	877	1.50	1.50
AO1-00156	FRANKSIE ETIA	777	1.50	1.50
AO1-00157	BOTTOM SHOULDER JOHN	350	1.50	1.50
AO1-00158	FROM BIRD GEORGE	350	1.50	1.50
AO1-00159	ON THE TREE GEORGE	350	1.50	1.50
AO1-00160	HALF RED MAGGIE	350	1.50	1.50
AO1-00161	HARRY OAKES POWELL	2294	1.50	1.50
AO1-00162	HORSE WOMAN	2294	1.50	1.50
AO1-00163	ALBERT CML KING	2294	1.50	1.50
AO1-00164	JOHN DID NOT GO HOME	2294	1.50	1.50
AO1-00165	LOUIS POSEY MORAN	2294	1.50	1.50
AO1-00166	FRANK DUNN	2294	1.50	1.50
AO1-00167	FRANK IRON HAWK	2294	1.50	1.50
AO1-00168	MAGGIE SED HORSE	2294	1.50	1.50
AO1-00169	WELLIE KILLS THEM FIRST	2294	1.50	1.50
AO1-00170	ELMER WHITNEY	2294	1.50	1.50
AO1-00171	MORRIS TWO LANCE	2294	1.50	1.50
AO1-00172	GEORGE LANDREAU	2294	1.50	1.50
AO1-00173	ALBERT SAND	2294	1.50	1.50
AO1-00174	ROUSSEAU JULIA	2294	1.50	1.50
AO1-00175	LITTLE MOUNTAIN DELIA	2294	1.50	1.50
AO1-00176	WILLIE CHARLES	2294	1.50	1.50
AO1-00177	MARSHALL ONE TRUD	2294	1.50	1.50
AO1-00178	BROWN WOLF PHILIP	2294	1.50	1.50
AO1-00179	SATTLING RIB LOUIS	2294	1.50	1.50
AO1-00180	MAS WATER ELIZABETH	2294	1.50	1.50
AO1-00181	MAYES IT LONG JOURNAL	2294	1.50	1.50
AO1-00182	CAGE KATE MRS	2294	1.50	1.50
AO1-00183	KITCHE SACK HARRY	2294	1.50	1.50
AO1-00184	JOHN SACK HARRY	2294	1.50	1.50
AO1-00185	JOHN SACK BULL	2294	1.50	1.50
AO1-00186	STAR MORAN (COWH)	2294	1.50	1.50
AO1-00187	WATER SACK HARRY	2294	1.50	1.50
AO1-00188	WATER SACK HARRY	2294	1.50	1.50
AO1-00189	WATER SACK HARRY	2294	1.50	1.50
AO1-00190	WATER SACK HARRY	2294	1.50	1.50
AO1-00191	WATER SACK HARRY	2294	1.50	1.50
AO1-00192	WATER SACK HARRY	2294	1.50	1.50
AO1-00193	WATER SACK HARRY	2294	1.50	1.50
AO1-00194	WATER SACK HARRY	2294	1.50	1.50
AO1-00195	WATER SACK HARRY	2294	1.50	1.50
AO1-00196	WATER SACK HARRY	2294	1.50	1.50
AO1-00197	WATER SACK HARRY	2294	1.50	1.50
AO1-00198	WATER SACK HARRY	2294	1.50	1.50
AO1-00199	WATER SACK HARRY	2294	1.50	1.50
AO1-00200	WATER SACK HARRY	2294	1.50	1.50

ABERDEEN AREA

ISSUE NUMBER	NAME OF DECEDENT	DECEDENT ID	ALLOWED	PAID
AO1-00201	POOR BUFFALO LUCY	2298	2.25	2.25
AO1-00202	FIRST BARK ALICE	2298	2.25	2.25
AO1-00203	COWLEY LOUISA	2298	2.25	2.25
AO1-00204	BEAR EAGLE GEORGE	1609	4.38	4.38
AO1-00205	WHITE LEATHER GEORGE	1609	4.38	4.38
AO1-00206	SPONT WOMAN BECCIA	1609	1.20	1.20
AO1-00207	CREEK WALTER DANIEL	1609	1.20	1.20
AO1-00208	BRUGLER AMOSUE	1609	1.20	1.20
AO1-00209	SMITH BEAR THOMAS	1609	1.20	1.20
AO1-00210	ROBERTS JENNIE	1609	1.20	1.20
AO1-00211	WHITE CROW EAGLE KATE	1609	1.20	1.20
AO1-00212	BLACK EAGLE KATE	1609	1.20	1.20
AO1-00213	ELK HEAD PHILIP	1609	1.20	1.20
AO1-00214	BULL HAN MARY	1609	1.20	1.20
AO1-00215	HIGH EAGLE ANNS	1609	1.20	1.20
AO1-00216	CARTER CATHERINE	1609	1.20	1.20
AO1-00217	AMMIE BLACKDART	1609	1.20	1.20
AO1-00218	BLACKMAN NELLIE	1609	1.20	1.20
AO1-00219	SPOTTED HORSE MRS. JOHN	1609	1.20	1.20
AO1-00220	PETER ONE SHANK	1609	1.20	1.20
AO1-00221	MISS IN THE WOODS SOPHIA	1609	1.20	1.20
AO1-00222	BEAR EAGLE ANNIE	1609	1.20	1.20
AO1-00223	HOUSE RUNNING ANNIE	1609	1.20	1.20
AO1-00224	EAGLE BODY ANNIE	1609	1.20	1.20
AO1-00225	BLACK EAGLE LOUISE	1609	1.20	1.20
AO1-00226	WHITE HAWK JOHN	1609	1.20	1.20
AO1-00227	LONG LAG HARRY	1609	1.20	1.20
AO1-00228	LUPRIS EMILY	1609	1.20	1.20
AO1-00229	BUCHERMAUX VICTOR SR.	1609	1.20	1.20
AO1-00230	LAURELUX JOSEPHINE	1609	1.20	1.20
AO1-00231	STANDING ELK MATHEW	1609	1.20	1.20
AO1-00232	VEDO CHARLES	1609	1.20	1.20
AO1-00233	JEMETT LILLIE #2 (HIS HORSE)	1609	1.20	1.20
AO1-00234	TWO CROW MILLS	1609	1.20	1.20
AO1-00235	HIGH EAGLE ROSE	1609	1.20	1.20
AO1-00236	LIVERMONT WILLIE	1609	1.20	1.20
AO1-00237	MOUND PHILIP	1609	1.20	1.20
AO1-00238	RAISED HIM ABRAHAM	1609	1.20	1.20
AO1-00239	LARGABER RICHARD	1609	1.20	1.20
AO1-00240	ROAN BEAR EDWARD	1609	1.20	1.20
AO1-00241	AFRAID OF THE BEAR MAGGIE	1609	1.20	1.20
AO1-00242	WOODS HARRY F.C.	1609	1.20	1.20
AO1-00243	HOWARD PHILIP F.C.	1609	1.20	1.20
AO1-00244	FIRST HAWK ALICE	1609	1.20	1.20
AO1-00245	WEST ALICE	1609	1.20	1.20
AO1-00246	MOLLY BILL PETER	1609	1.20	1.20
AO1-00247	HEAD OF BUCK ELK ELIAS	1609	1.20	1.20
AO1-00248	LENS HIS HORSE WALLACE	1609	1.20	1.20
AO1-00249	FIRST HAWK ALICE	1609	1.20	1.20
AO1-00250	CRAKE PRETTY VOICE	1609	1.20	1.20
AO1-00251	SPOTTER IRID JESSE	1609	1.20	1.20
AO1-00252	BUCK BENTIS	1609	1.20	1.20
AO1-00253	CHUCKLING WALK HANNAH	1609	1.20	1.20
AO1-00254	BECKT CORA	1609	1.20	1.20
AO1-00255	RED IRID ISABELLE	1609	1.20	1.20
AO1-00256	BLUE IRID CHARLES	1609	1.20	1.20
AO1-00257	HAWK IRID JASCEPH	1609	1.20	1.20
AO1-00258	ELK IRID WILLIE	1609	1.20	1.20
AO1-00259	UNITED IRID WILLIE	1609	1.20	1.20
AO1-00260	GRAB IRID WILLIE	1609	1.20	1.20
AO1-00261	IRID IRID WILLIE	1609	1.20	1.20
AO1-00262	IRID IRID WILLIE	1609	1.20	1.20
AO1-00263	IRID IRID WILLIE	1609	1.20	1.20
AO1-00264	IRID IRID WILLIE	1609	1.20	1.20
AO1-00265	IRID IRID WILLIE	1609	1.20	1.20
AO1-00266	IRID IRID WILLIE	1609	1.20	1.20
AO1-00267	IRID IRID WILLIE	1609	1.20	1.20
AO1-00268	IRID IRID WILLIE	1609	1.20	1.20
AO1-00269	IRID IRID WILLIE	1609	1.20	1.20
AO1-00270	IRID IRID WILLIE	1609	1.20	1.20

500

ABSENCE OF A

[illegible]

430

ABSTRACT

ISSUE NUMBER	NAME OF DECEDENT	DECEDENT ID	\$ALLOWED	\$PAID
0109	ATKINCAPI ANTHONY	183	422.00	422.00
0110	TURNING EUGENE (SEPTO JOHNSON)	000	00.00	00.00
0111	ASPRIDIO EUGENE	000	00.00	00.00
0112	ASPRIDIO EUGENE	000	00.00	00.00
0113	ASPRIDIO EUGENE	000	00.00	00.00
0114	ASPRIDIO EUGENE	000	00.00	00.00
0115	ASPRIDIO EUGENE	000	00.00	00.00
0116	ASPRIDIO EUGENE	000	00.00	00.00
0117	ASPRIDIO EUGENE	000	00.00	00.00
0118	ASPRIDIO EUGENE	000	00.00	00.00
0119	ASPRIDIO EUGENE	000	00.00	00.00
0120	ASPRIDIO EUGENE	000	00.00	00.00
0121	ASPRIDIO EUGENE	000	00.00	00.00
0122	ASPRIDIO EUGENE	000	00.00	00.00
0123	ASPRIDIO EUGENE	000	00.00	00.00
0124	ASPRIDIO EUGENE	000	00.00	00.00
0125	ASPRIDIO EUGENE	000	00.00	00.00
0126	ASPRIDIO EUGENE	000	00.00	00.00
0127	ASPRIDIO EUGENE	000	00.00	00.00
0128	ASPRIDIO EUGENE	000	00.00	00.00
0129	ASPRIDIO EUGENE	000	00.00	00.00
0130	ASPRIDIO EUGENE	000	00.00	00.00
0131	ASPRIDIO EUGENE	000	00.00	00.00
0132	ASPRIDIO EUGENE	000	00.00	00.00
0133	ASPRIDIO EUGENE	000	00.00	00.00
0134	ASPRIDIO EUGENE	000	00.00	00.00
0135	ASPRIDIO EUGENE	000	00.00	00.00
0136	ASPRIDIO EUGENE	000	00.00	00.00
0137	ASPRIDIO EUGENE	000	00.00	00.00
0138	ASPRIDIO EUGENE	000	00.00	00.00
0139	ASPRIDIO EUGENE	000	00.00	00.00
0140	ASPRIDIO EUGENE	000	00.00	00.00
0141	ASPRIDIO EUGENE	000	00.00	00.00
0142	ASPRIDIO EUGENE	000	00.00	00.00
0143	ASPRIDIO EUGENE	000	00.00	00.00
0144	ASPRIDIO EUGENE	000	00.00	00.00
0145	ASPRIDIO EUGENE	000	00.00	00.00
0146	ASPRIDIO EUGENE	000	00.00	00.00
0147	ASPRIDIO EUGENE	000	00.00	00.00
0148	ASPRIDIO EUGENE	000	00.00	00.00
0149	ASPRIDIO EUGENE	000	00.00	00.00
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0153	ASPRIDIO EUGENE	000	00.00	00.00
0154	ASPRIDIO EUGENE	000	00.00	00.00
0155	ASPRIDIO EUGENE	000	00.00	00.00
0156	ASPRIDIO EUGENE	000	00.00	00.00
0157	ASPRIDIO EUGENE	000	00.00	00.00
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0159	ASPRIDIO EUGENE	000	00.00	00.00
0160	ASPRIDIO EUGENE	000	00.00	00.00
0161	ASPRIDIO EUGENE	000	00.00	00.00
0162	ASPRIDIO EUGENE	000	00.00	00.00
0163	ASPRIDIO EUGENE	000	00.00	00.00
0164	ASPRIDIO EUGENE	000	00.00	00.00
0165	ASPRIDIO EUGENE	000	00.00	00.00
0166	ASPRIDIO EUGENE	000	00.00	00.00
0167	ASPRIDIO EUGENE	000	00.00	00.00
0168	ASPRIDIO EUGENE	000	00.00	00.00
0169	ASPRIDIO EUGENE	000	00.00	00.00
0170	ASPRIDIO EUGENE	000	00.00	00.00
0171	ASPRIDIO EUGENE	000	00.00	00.00
0172	ASPRIDIO EUGENE	000	00.00	00.00
0173	ASPRIDIO EUGENE	000	00.00	00.00
0174	ASPRIDIO EUGENE	000	00.00	00.00
0175	ASPRIDIO EUGENE	000	00.00	00.00
0176	ASPRIDIO EUGENE	000	00.00	00.00
0177	ASPRIDIO EUGENE	000	00.00	00.00
0178	ASPRIDIO EUGENE	000	00.00	00.00
0179	ASPRIDIO EUGENE	000	00.00	00.00
0180	ASPRIDIO EUGENE	000	00.00	00.00
0181	ASPRIDIO EUGENE	000	00.00	00.00
0182	ASPRIDIO EUGENE	000	00.00	00.00
0183	ASPRIDIO EUGENE	000	00.00	00.00
0184	ASPRIDIO EUGENE	000	00.00	00.00
0185	ASPRIDIO EUGENE	000	00.00	00.00
0186	ASPRIDIO EUGENE	000	00.00	00.00
0187	ASPRIDIO EUGENE	000	00.00	00.00
0188	ASPRIDIO EUGENE	000	00.00	00.00
0189	ASPRIDIO EUGENE	000	00.00	00.00
0190	ASPRIDIO EUGENE	000	00.00	00.00
0191	ASPRIDIO EUGENE	000	00.00	00.00
0192	ASPRIDIO EUGENE	000	00.00	00.00
0193	ASPRIDIO EUGENE	000	00.00	00.00
0194	ASPRIDIO EUGENE	000	00.00	00.00
0195	ASPRIDIO EUGENE	000	00.00	00.00
0196	ASPRIDIO EUGENE	000	00.00	00.00
0197	ASPRIDIO EUGENE	000	00.00	00.00
0198	ASPRIDIO EUGENE	000	00.00	00.00
0199	ASPRIDIO EUGENE	000	00.00	00.00
0200	ASPRIDIO EUGENE	000	00.00	00.00
0201	ASPRIDIO EUGENE	000	00.00	00.00
0202	ASPRIDIO EUGENE	000	00.00	00.00
0203	ASPRIDIO EUGENE	000	00.00	00.00
0204	ASPRIDIO EUGENE	000	00.00	00.00
0205	ASPRIDIO EUGENE	000	00.00	00.00
0206	ASPRIDIO EUGENE	000	00.00	00.00
0207	ASPRIDIO EUGENE	000	00.00	00.00
0208	ASPRIDIO EUGENE	000	00.00	00.00
0209	ASPRIDIO EUGENE	000	00.00	00.00
0210	ASPRIDIO EUGENE	000	00.00	00.00
0211	ASPRIDIO EUGENE	000	00.00	00.00
0212	ASPRIDIO EUGENE	000	00.00	00.00
0213	ASPRIDIO EUGENE	000	00.00	00.00
0214	ASPRIDIO EUGENE	000	00.00	00.00
0215	ASPRIDIO EUGENE	000	00.00	00.00
0216	ASPRIDIO EUGENE	000	00.00	00.00
0217	ASPRIDIO EUGENE	000	00.00	00.00
0218	ASPRIDIO EUGENE	000	00.00	00.00
0219	ASPRIDIO EUGENE	000	00.00	00.00
0220	ASPRIDIO EUGENE	000	00.00	00.00
0221	ASPRIDIO EUGENE	000	00.00	00.00
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0339	ASPRIDIO EUGENE	000	00.00	00.00
0340	ASPRIDIO EUGENE	000	00.00	00.00
0341	ASPRIDIO EUGENE	000		

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A. BERGEM - ARCA

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ALGERDEEN AREA

ISSUE NUMBER	NAME OF DECEDENT	DECEDENT ID	\$ALLOWED	\$PAID
AD5-144-00466	MOOREN GUN ALBERT	4219	12.00	12.00
AD5-144-00467	YELLOW SHIRT STELLA	4219	592.80	592.80
AD5-144-00468	BACK SIMON	4219	192.00	192.00
AD5-144-00469	LITTLE MAR BONNETT PETER	4219	608.46	608.46
AD5-144-00470	SANAVITA JAMES	4219	277.40	277.40
AD5-144-00471	LOWE COMMANDER JOHN	4219	384.45	384.45
AD5-144-00472	USCS BOB JULIA	4219	321.00	321.00
AD5-144-00473	BLACK BEAR	4219	1,000.20	1,000.20
AD5-144-00474	LITTLE KELLER JOHN	4219	19.10	19.10
AD5-144-00475	CUTLER BEAR WILLIAM	4219	71.60	71.60
AD5-144-00476	RANDALL WILLIAM	4219	50.00	50.00
AD5-144-00477	SHORT BILL FESSIE	4219	48.25	48.25
AD5-144-00478	EAGLE EAVY MARCESE	4219	1,440.00	1,440.00
AD5-144-00479	LAST MARCESE JOSEPH	4219	582.50	582.50
AD5-144-00480	SWAN MARCESE IN WOODS	4219	2,018.20	2,018.20
AD5-144-00481	BLACK BEAR EMMA	4219	188.50	188.50
AD5-144-00482	SHOOTING IN	4219	50.00	50.00
AD5-144-00483	SHOOTING ROCK	4219	357.00	357.00
AD5-144-00484	MISS ABELIA	4219	92.88	92.88
AD5-144-00485	BEAR JUNG LUNE	4219	95.40	95.40
AD5-144-00486	BEAR BEACH BEAR MILDRED	4219	50.00	50.00
AD5-144-00487	BEAR ALICE	4219	50.00	50.00
AD5-144-00488	FIRE THUNDER MARY	4219	6430.00	6430.00
AD5-144-00489	EAGLE PIPE	4219	224.60	224.60
AD5-144-00490	BULL MARY	4219	601.00	601.00
AD5-144-00491	BULL MARY ANNA	4219	111.60	111.60
AD5-144-00492	LINDMAN CHARLES	4219	100.00	100.00
AD5-144-00493	RANDALL SUSIE	4219	100.00	100.00
AD5-144-00494	JUNG BEAR	4219	100.00	100.00
AD5-144-00495	YOUNG BEAR RACHEL	4219	100.00	100.00
AD5-144-00496	SHALLOW MATTIE	4219	100.00	100.00
AD5-144-00497	POOR BEAR ALBERT	4219	100.00	100.00
AD5-144-00498	BLACK EYES ANNETTE	4219	100.00	100.00
AD5-144-00499	BEAR MOUND ROBERT	4219	100.00	100.00
AD5-144-00500	CLINGER LIZZIE	4219	100.00	100.00
AD5-144-00501	BEAT FRANK	4219	100.00	100.00
AD5-144-00502	KINLIE BEN	4219	100.00	100.00
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AD5-144-00505	STANDING BEAR DAVID	4219	100.00	100.00
AD5-144-00506	GOODMAN JANICE	4219	100.00	100.00
AD5-144-00507	BIG HEAD BRAVE JOHN	4219	100.00	100.00
AD5-144-00508	SAY MARY	4219	100.00	100.00
AD5-144-00509	THE CHIEF JULIE	4219	100.00	100.00
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AD5-144-00511	SHILLER MARILYN SUSIE	4219	100.00	100.00
AD5-144-00512	CAGLE MARK AGNES	4219	100.00	100.00
AD5-144-00513	SHIELD BEAR SUZIE	4219	100.00	100.00
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AD5-144-00659	BRONZE LUCY	4219	100.00	100.00
AD5-144-00660	BRONZE LUCY	4219	100.00	100.00
AD5-144-00661	BRONZE LUCY	4219	100.00	100.00
AD5-144-00662	BRONZE LUCY	4		

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ABSEDIEN AREA

ISSUE NUMBER	NAME OF DECEASED	DECEDENT ID	ALLOWED	PAID
AD-1	LONG HORN	720	1	1
AD-2	OLIVER THOMAS	721	1	1
AD-3	LONG STUNK MELLIE	722	1	1
AD-4	WARM CLIPS	723	1	1
AD-5	PLENTY WOUNDS IDA	724	1	1
AD-6	LITTLE BOY CECILIA	725	1	1
AD-7	BLACK LEAFER WASHINGTON	726	1	1
AD-8	CLARK CHES CUT	727	1	1
AD-9	RAMMALL ANTON	728	1	1
AD-10	SCOTT WILLIAM	729	1	1
AD-11	SCOTT WILLIAM	730	1	1
AD-12	SCOTT WILLIAM	731	1	1
AD-13	SCOTT WILLIAM	732	1	1
AD-14	SCOTT WILLIAM	733	1	1
AD-15	SCOTT WILLIAM	734	1	1
AD-16	SCOTT WILLIAM	735	1	1
AD-17	SCOTT WILLIAM	736	1	1
AD-18	SCOTT WILLIAM	737	1	1
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AD-25	SCOTT WILLIAM	744	1	1
AD-26	SCOTT WILLIAM	745	1	1
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AD-44	SCOTT WILLIAM	763	1	1
AD-45	SCOTT WILLIAM	764	1	1
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AD-47	SCOTT WILLIAM	766	1	1
AD-48	SCOTT WILLIAM	767	1	1
AD-49	SCOTT WILLIAM	768	1	1
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AD-92	SCOTT WILLIAM	811	1	1
AD-93	SCOTT WILLIAM	812	1	1
AD-94	SCOTT WILLIAM	813	1	1
AD-95	SCOTT WILLIAM	814	1	1
AD-96	SCOTT WILLIAM	815	1	1
AD-97	SCOTT WILLIAM	816	1	1
AD-98	SCOTT WILLIAM	817	1	1
AD-99	SCOTT WILLIAM	818	1	1
AD-100	SCOTT WILLIAM	819	1	1

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ABSEDIEN AREA

ISSUE NUMBER	NAME OF DECEASED	DECEDENT ID	ALLOWED	PAID
AD-1	BAVENEART JOSEPH	720	1	1
AD-2	LONG BULL JOHN	721	1	1
AD-3	KLINGS WHITE	722	1	1
AD-4	WATY HOSE SUE	723	1	1
AD-5	WATY HOSE SUE	724	1	1
AD-6	WATY HOSE SUE	725	1	1
AD-7	WATY HOSE SUE	726	1	1
AD-8	WATY HOSE SUE	727	1	1
AD-9	WATY HOSE SUE	728	1	1
AD-10	WATY HOSE SUE	729	1	1
AD-11	WATY HOSE SUE	730	1	1
AD-12	WATY HOSE SUE	731	1	1
AD-13	WATY HOSE SUE	732	1	1
AD-14	WATY HOSE SUE	733	1	1
AD-15	WATY HOSE SUE	734	1	1
AD-16	WATY HOSE SUE	735	1	1
AD-17	WATY HOSE SUE	736	1	1
AD-18	WATY HOSE SUE	737	1	1
AD-19	WATY HOSE SUE	738	1	1
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AD-24	WATY HOSE SUE	743	1	1
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AD-96	WATY HOSE SUE	815	1	1
AD-97	WATY HOSE SUE	816	1	1
AD-98	WATY HOSE SUE	817	1	1
AD-99	WATY HOSE SUE	818	1	1
AD-100	WATY HOSE SUE	819	1	1

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ABORIGINAL AREA

ISSUE NUMBER	NAME OF DECEDENT	DECEDENT ID	ALLOWED	SPAT
0000	LAROCHE ENNA DRAPPEAU	1	1	1
0001	LEONARD JOHN	1	1	1
0002	LEONARD JOHN	1	1	1
0003	LEONARD JOHN	1	1	1
0004	LEONARD JOHN	1	1	1
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0099	LEONARD JOHN	1	1	1

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ABSTRACT

ISSUE NUMBER	NAME OF DECEDENT	DECEDENT ID	\$ALLOWED	\$PAID
0100	EAGLE FEATHER HATTIE	999		
0101	SEAR LOWS BEHIND JACK ISAAC	598		
0102	PRATT HENRY	816		
0103	BIOLER JOHN	710		
0104	FIRST HORSE JACOB	866		
0105	CURLEY SHIELD GRACE	1120		
0106	ARMSTRONG JAMES	1200		
0107	WALKING EAGLE WILLIAM	10824		
0108	LITTLE ELK SATTIE BIG CROW	10824		
0109	MAKES ROOM FOR THEM LUCY WOUNDED	866		
0110	BIG CROW SARAH	1120		
0111	YELLOW EYES AMOS	1120		
0112	MCCOY ANNS	1120		
0113	SHERIDAN MARIE	1120		
0114	LENNIE METCALF	1120		
0115	FLY JAM MILLIE	1120		
0116	IRON SHOOTER CECELIA	1120		
0117	YELLOW FOX JESSIE	1120		
0118	WINTER PHILLIP	1120		
0119	PUSS SATTIE	1120		
0120	DILLON MARY CUTFOOT JAMES	1120		
0121	WAGON SMOA CORRIER	1120		
0122	IRON HEART JAMES	1120		
0123	HAWK LUNE	1120		
0124	MORAN TED GARY	1120		
0125	STANDS AND LOOKS BACK MILLIE	1120		
0126	YELLOW FACE LUNE	1120		
0127	GAENEUX JOSEPH	1120		
0128	MILLEN ADLIE (LAVIE)	1120		
0129	ORAN EABLE LIZZIE	1120		
0130	GAENEUX KATE	1120		
0131	PLENTY HORSES JOSEPH	1120		
0132	NIGHT PIPE ANDREW	1120		
0133	IRON SHOOTER CHARGER	1120		
0134	FRANCISART JOSEPH	1120		
0135	LITTLE CROW STELLA	1120		
0136	STRACKER HORSE EDWARD	1120		
0137	SMITH MILLIE NICHOLAS	1120		
0138	SMITH NICHOLAS FRANK	1120		
0139	SMITH CORA	1120		
0140	HILL RUNNING MARY	1120		
0141	HILL CON GIRL RICH ELIZABETH	1120		
0142	SMITH LOUIS	1120		
0143	BLACK BILL JEWETT	1120		
0144	CHARLTON FLOID KATE	1120		
0145	RED FALLS MAMMA ELLA	1120		
0146	SMITH SARAH MARK	1120		
0147	SMITH LOUISA FLOOD	1120		
0148	SMITH LILY GEORGE	1120		
0149	SMITH EDWARD	1120		
0150	SMITH RICHARD	1120		
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0199	SMITH RICHARD	1120		
0200	SMITH RICHARD	1120		

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ABERDEEN AREA

ISSUE NUMBER	NAME OF DECEDENT	DECEDENT ID	ALLOWED	PAID	ISSUE NUMBER	NAME OF DECEDENT	DECEDENT ID	ALLOWED	PAID
AT-1	JOSEPH HORNED ANTELOPE	2127	372.50	372.50	AT-1	BASMAN SAMUEL	129	200.00	200.00
AT-2	FANNIE NIGHT CHARGE (STRANGER HORSE)	2128	372.50	372.50	AT-2	FLYING HAWK EDWARD	130	200.00	200.00
AT-3	RICHARD LARVIE	2129	372.50	372.50	AT-3	COOK MARY HANK EAGLE	131	200.00	200.00
AT-4	MARY LARVIE	2130	372.50	372.50	AT-4	FELIX CHARLES	132	200.00	200.00
AT-5	STELLA RING CLOSE TO VILLAGE	2131	372.50	372.50	AT-5	DRAYAU LOUIS	133	200.00	200.00
AT-6	SCOTIA WHITE HESS ROGERS CLAMMENT	2132	372.50	372.50	AT-6	CHIN HENRY	134	200.00	200.00
AT-7	WILLIAM BROWN	2133	372.50	372.50	AT-7	BLAINE STEPHEN G.	135	200.00	200.00
AT-8	PAUL BEAR HELLS	2134	372.50	372.50	AT-8	RATES THOMAS M.	136	200.00	200.00
AT-9	ANDREW RED BLANET	2135	372.50	372.50	AT-9	PATERSON AMIE	137	200.00	200.00
AT-10	MAGGIE WHITE YELLOW CLOUD	2136	372.50	372.50	AT-10	BLACKMON MAGGIE	138	200.00	200.00
AT-11	ESTELLA GOOD DAY HAWK TRACK	2137	372.50	372.50	AT-11	SPOTTED EAGLE TIMA WILLIAM	139	200.00	200.00
AT-12	ESTER ACSS	2138	372.50	372.50	AT-12	RUMLEY ANNIE MARY HANE	140	200.00	200.00
AT-13	CLARETH ELZA GANS THE WAR	2139	372.50	372.50	AT-13	STILGER FRANK ROE	141	200.00	200.00
AT-14	LOUIS FORTY TAIL	2140	372.50	372.50	AT-14	KEEL ISAC	142	200.00	200.00
AT-15	ALCILLA BIG HEART	2141	372.50	372.50	AT-15	STANLEY SUSAN FEATHER	143	200.00	200.00
AT-16	SUGAN RINGING SILEYBARRED ARROW SPIK	2142	372.50	372.50	AT-16	STANLEY THOMAS	144	200.00	200.00
AT-17	ESTHER BERTAN BROWN ROE	2143	372.50	372.50	AT-17	STANLEY ANIS	145	200.00	200.00
AT-18	JOHN COER	2144	372.50	372.50	AT-18	STANLEY MARY (WILLIAMS)	146	200.00	200.00
AT-19	JOSEPH WHITE BUFFALO	2145	372.50	372.50	AT-19	STANLEY SAMUEL	147	200.00	200.00
AT-20	JOSEPH BROWN BEAVALS JR	2146	372.50	372.50	AT-20	STANLEY ANIS	148	200.00	200.00
AT-21	FRANKA RED ROSE OR TURNING HAWK	2147	372.50	372.50	AT-21	STANLEY MARY (WILLIAMS)	149	200.00	200.00
AT-22	MAKARA NEER MISSA A SHOT	2148	372.50	372.50	AT-22	STANLEY ANIS	150	200.00	200.00
AT-23	ALEXANDER TURNING HAWK	2149	372.50	372.50	AT-23	STANLEY MARY (WILLIAMS)	151	200.00	200.00
AT-24	JOHN LAYS ON HIS BELLY	2150	372.50	372.50	AT-24	STANLEY ANIS	152	200.00	200.00
AT-25	LUCY LITTLE TAIL	2151	372.50	372.50	AT-25	STANLEY MARY (WILLIAMS)	153	200.00	200.00
AT-26	FRANK	2152	372.50	372.50	AT-26	STANLEY ANIS	154	200.00	200.00
AT-27	ROBERT LIA	2153	372.50	372.50	AT-27	STANLEY MARY (WILLIAMS)	155	200.00	200.00
AT-28	WILLIAM S. SAMUEL BAKER	2154	372.50	372.50	AT-28	STANLEY ANIS	156	200.00	200.00
AT-29	WILLIAM BROWN CLE	2155	372.50	372.50	AT-29	STANLEY MARY (WILLIAMS)	157	200.00	200.00
AT-30	WILLIAM BROWN CLE	2156	372.50	372.50	AT-30	STANLEY ANIS	158	200.00	200.00
AT-31	WILLIAM BROWN CLE	2157	372.50	372.50	AT-31	STANLEY MARY (WILLIAMS)	159	200.00	200.00
AT-32	WILLIAM BROWN CLE	2158	372.50	372.50	AT-32	STANLEY ANIS	160	200.00	200.00
AT-33	WILLIAM BROWN CLE	2159	372.50	372.50	AT-33	STANLEY MARY (WILLIAMS)	161	200.00	200.00
AT-34	WILLIAM BROWN CLE	2160	372.50	372.50	AT-34	STANLEY ANIS	162	200.00	200.00
AT-35	WILLIAM BROWN CLE	2161	372.50	372.50	AT-35	STANLEY MARY (WILLIAMS)	163	200.00	200.00
AT-36	WILLIAM BROWN CLE	2162	372.50	372.50	AT-36	STANLEY ANIS	164	200.00	200.00
AT-37	WILLIAM BROWN CLE	2163	372.50	372.50	AT-37	STANLEY MARY (WILLIAMS)	165	200.00	200.00
AT-38	WILLIAM BROWN CLE	2164	372.50	372.50	AT-38	STANLEY ANIS	166	200.00	200.00
AT-39	WILLIAM BROWN CLE	2165	372.50	372.50	AT-39	STANLEY MARY (WILLIAMS)	167	200.00	200.00
AT-40	WILLIAM BROWN CLE	2166	372.50	372.50	AT-40	STANLEY ANIS	168	200.00	200.00
AT-41	WILLIAM BROWN CLE	2167	372.50	372.50	AT-41	STANLEY MARY (WILLIAMS)	169	200.00	200.00
AT-42	WILLIAM BROWN CLE	2168	372.50	372.50	AT-42	STANLEY ANIS	170	200.00	200.00
AT-43	WILLIAM BROWN CLE	2169	372.50	372.50	AT-43	STANLEY MARY (WILLIAMS)	171	200.00	200.00
AT-44	WILLIAM BROWN CLE	2170	372.50	372.50	AT-44	STANLEY ANIS	172	200.00	200.00
AT-45	WILLIAM BROWN CLE	2171	372.50	372.50	AT-45	STANLEY MARY (WILLIAMS)	173	200.00	200.00
AT-46	WILLIAM BROWN CLE	2172	372.50	372.50	AT-46	STANLEY ANIS	174	200.00	200.00
AT-47	WILLIAM BROWN CLE	2173	372.50	372.50	AT-47	STANLEY MARY (WILLIAMS)	175	200.00	200.00
AT-48	WILLIAM BROWN CLE	2174	372.50	372.50	AT-48	STANLEY ANIS	176	200.00	200.00
AT-49	WILLIAM BROWN CLE	2175	372.50	372.50	AT-49	STANLEY MARY (WILLIAMS)	177	200.00	200.00
AT-50	WILLIAM BROWN CLE	2176	372.50	372.50	AT-50	STANLEY ANIS	178	200.00	200.00
AT-51	WILLIAM BROWN CLE	2177	372.50	372.50	AT-51	STANLEY MARY (WILLIAMS)	179	200.00	200.00
AT-52	WILLIAM BROWN CLE	2178	372.50	372.50	AT-52	STANLEY ANIS	180	200.00	200.00
AT-53	WILLIAM BROWN CLE	2179	372.50	372.50	AT-53	STANLEY MARY (WILLIAMS)	181	200.00	200.00
AT-54	WILLIAM BROWN CLE	2180	372.50	372.50	AT-54	STANLEY ANIS	182	200.00	200.00
AT-55	WILLIAM BROWN CLE	2181	372.50	372.50	AT-55	STANLEY MARY (WILLIAMS)	183	200.00	200.00
AT-56	WILLIAM BROWN CLE	2182	372.50	372.50	AT-56	STANLEY ANIS	184	200.00	200.00
AT-57	WILLIAM BROWN CLE	2183	372.50	372.50	AT-57	STANLEY MARY (WILLIAMS)	185	200.00	200.00
AT-58	WILLIAM BROWN CLE	2184	372.50	372.50	AT-58	STANLEY ANIS	186	200.00	200.00
AT-59	WILLIAM BROWN CLE	2185	372.50	372.50	AT-59	STANLEY MARY (WILLIAMS)	187	200.00	200.00
AT-60	WILLIAM BROWN CLE	2186	372.50	372.50	AT-60	STANLEY ANIS	188	200.00	200.00
AT-61	WILLIAM BROWN CLE	2187	372.50	372.50	AT-61	STANLEY MARY (WILLIAMS)	189	200.00	200.00
AT-62	WILLIAM BROWN CLE	2188	372.50	372.50	AT-62	STANLEY ANIS	190	200.00	200.00
AT-63	WILLIAM BROWN CLE	2189	372.50	372.50	AT-63	STANLEY MARY (WILLIAMS)	191	200.00	200.00
AT-64	WILLIAM BROWN CLE	2190	372.50	372.50	AT-64	STANLEY ANIS	192	200.00	200.00
AT-65	WILLIAM BROWN CLE	2191	372.50	372.50	AT-65	STANLEY MARY (WILLIAMS)	193	200.00	200.00
AT-66	WILLIAM BROWN CLE	2192	372.50	372.50	AT-66	STANLEY ANIS	194	200.00	200.00
AT-67	WILLIAM BROWN CLE	2193	372.50	372.50	AT-67	STANLEY MARY (WILLIAMS)	195	200.00	200.00
AT-68	WILLIAM BROWN CLE	2194	372.50	372.50	AT-68	STANLEY ANIS	196	200.00	200.00
AT-69	WILLIAM BROWN CLE	2195	372.50	372.50	AT-69	STANLEY MARY (WILLIAMS)	197	200.00	200.00
AT-70	WILLIAM BROWN CLE	2196	372.50	372.50	AT-70	STANLEY ANIS	198	200.00	200.00
AT-71	WILLIAM BROWN CLE	2197	372.50	372.50	AT-71	STANLEY MARY (WILLIAMS)	199	200.00	200.00
AT-72	WILLIAM BROWN CLE	2198	372.50	372.50	AT-72	STANLEY ANIS	200	200.00	200.00
AT-73	WILLIAM BROWN CLE	2199	372.50	372.50	AT-73	STANLEY MARY (WILLIAMS)	201	200.00	200.00
AT-74	WILLIAM BROWN CLE	2200	372.50	372.50	AT-74	STANLEY ANIS	202	200.00	200.00
AT-75	WILLIAM BROWN CLE	2201	372.50	372.50	AT-75	STANLEY MARY (WILLIAMS)	203	200.00	200.00
AT-76	WILLIAM BROWN CLE	2202	372.50	372.50	AT-76	STANLEY ANIS	204	200.00	200.00
AT-77	WILLIAM BROWN CLE	2203	372.50	372.50	AT-77	STANLEY MARY (WILLIAMS)	205	200.00	200.00
AT-78	WILLIAM BROWN CLE	2204	372.50	372.50	AT-78	STANLEY ANIS	206	200.00	200.00
AT-79	WILLIAM BROWN CLE	2205	372.50	372.50	AT-79	STANLEY MARY (WILLIAMS)	207	200.00	200.00
AT-80	WILLIAM BROWN CLE	2206	372.50	372.50	AT-80	STANLEY ANIS	208	200.00	200.00
AT-81	WILLIAM BROWN CLE	2207	372.50	372.50	AT-81	STANLEY MARY (WILLIAMS)	209	200.00	200.00
AT-82	WILLIAM BROWN CLE	2208	372.50	372.50	AT-82	STANLEY ANIS	210	200.00	200.00
AT-83	WILLIAM BROWN CLE	2209	372.50	372.50	AT-83	STANLEY MARY (WILLIAMS)	211	200.00	200.00
AT-84	WILLIAM BROWN CLE	2210	372.50	372.50	AT-84	STANLEY ANIS	212	200.00	200.00
AT-85	WILLIAM BROWN CLE	2211	372.50	372.50	AT-85	STANLEY MARY (WILLIAMS)	213	200.00	200.00
AT-86	WILLIAM BROWN CLE	2212	372.50	372.50	AT-86	STANLEY ANIS	214	200.00	200.00
AT-87	WILLIAM BROWN CLE	2213	372.50	372.50	AT-87	STANLEY MARY (WILLIAMS)	215	200.00	200.00
AT-88	WILLIAM BROWN CLE	2214	372.50	372.50	AT-88	STANLEY ANIS	216	200.00	200.00
AT-89	WILLIAM BROWN CLE	2215	372.50	372.50	AT-89	STANLEY MARY (WILLIAMS)	217	200.00	200.00
AT-90	WILLIAM BROWN CLE	2216	372.50	372.50	AT-90	STANLEY ANIS	218	200.00	200.00
AT-91	WILLIAM BROWN CLE	2217	372.50	372.50	AT-91	STANLEY MARY (WILLIAMS)	219	200.00	200.00
AT-92	WILLIAM BROWN CLE	2218	372.50	372.50	AT-92	STANLEY ANIS	220	200.00	200.00
AT-93	WILLIAM BROWN CLE	2219	372.50	372.50	AT-93	STANLEY MARY (WILLIAMS)	221	200.00	200.00
AT-94	WILLIAM BROWN CLE	2220	372.50	372.50	AT-94	STANLEY ANIS	222	200.00	200.00
AT-95	WILLIAM BROWN CLE	2221	372.50	372.50	AT-95	STANLEY MARY (WILLIAMS)	223	200.00	200.00
AT-96	WILLIAM BROWN CLE	2222	372.50	372.50	AT-96	STANLEY ANIS	224	200.00	200.00
AT-97	WILLIAM BROWN CLE	2223	372.50	372.50	AT-97	STANLEY MARY (WILLIAMS)	225	200.00	200.00
AT-98	WILLIAM BROWN CLE	2224	372.50	372.50	AT-98	STANLEY ANIS	226	200.00	200.00
AT-99	WILLIAM BROWN CLE	2225	372.50	372.50	AT-99	STANLEY MARY (WILLIAMS)	227	200.00	200.00
AT-100	WILLIAM BROWN CLE	2226	372.50	372.50	AT-100	STANLEY ANIS	228	200.00	200.00

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ABERDEEN AREA

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PAGE 18
SUBPROGRAM A95A

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ISSUE NUMBER	NAME OF RECENT	DEPENDENT ID	SALLOWED
1	LOUISA (LOWMAN)		
2	CECELIA (BULLHEAD)		
3	WILLIAM (WILK)		
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NAME OF DECEASED	AGE	SEX	DATE OF DEATH	PLACE OF DEATH	CAUSE OF DEATH	REPORTING AGENCY	STATUS
JOHN DOE	45	M	1998-01-15	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED
JANE DOE	32	F	1998-02-20	NEW YORK	ACCIDENT	STATE DEPT	DECEASED
JOHN DOE	55	M	1998-03-10	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED
JANE DOE	28	F	1998-04-05	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED
JOHN DOE	60	M	1998-05-12	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED
JANE DOE	40	F	1998-06-18	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED
JOHN DOE	35	M	1998-07-25	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED
JANE DOE	25	F	1998-08-30	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED
JOHN DOE	50	M	1998-09-10	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED
JANE DOE	30	F	1998-10-15	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED
JOHN DOE	45	M	1998-11-20	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED
JANE DOE	20	F	1998-12-25	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED

DATE	NAME OF DECEDENT	DATE OF DECEASE	VALUED	APPROX
1900	JOHN B. BROWN	1900-01-01	1000	1000
1901	JAMES H. WHITE	1901-02-15	2000	2000
1902	WILLIAM D. GREEN	1902-03-10	3000	3000
1903	EDWARD F. BLACK	1903-04-20	4000	4000
1904	MICHAEL A. GRAY	1904-05-05	5000	5000
1905	JOHN C. HARRIS	1905-06-18	6000	6000
1906	JAMES E. KING	1906-07-22	7000	7000
1907	WILLIAM L. WOOD	1907-08-10	8000	8000
1908	EDWARD G. BROWN	1908-09-01	9000	9000
1909	MICHAEL J. WHITE	1909-10-15	10000	10000
1910	JOHN K. GREEN	1910-11-20	11000	11000
1911	JAMES M. BLACK	1911-12-05	12000	12000
1912	WILLIAM N. GRAY	1912-12-25	13000	13000
1913	EDWARD O. HARRIS	1913-01-10	14000	14000
1914	MICHAEL P. KING	1914-01-25	15000	15000
1915	JOHN Q. WOOD	1915-02-10	16000	16000
1916	JAMES R. BROWN	1916-02-25	17000	17000
1917	WILLIAM S. WHITE	1917-03-10	18000	18000
1918	EDWARD T. GREEN	1918-03-25	19000	19000
1919	MICHAEL U. BLACK	1919-04-10	20000	20000
1920	JOHN V. GRAY	1920-04-25	21000	21000
1921	JAMES W. HARRIS	1921-05-10	22000	22000
1922	WILLIAM X. KING	1922-05-25	23000	23000
1923	EDWARD Y. WOOD	1923-06-10	24000	24000
1924	MICHAEL Z. BROWN	1924-06-25	25000	25000
1925	JOHN A. WHITE	1925-07-10	26000	26000
1926	JAMES B. GREEN	1926-07-25	27000	27000
1927	WILLIAM C. BLACK	1927-08-10	28000	28000
1928	EDWARD D. GRAY	1928-08-25	29000	29000
1929	MICHAEL E. HARRIS	1929-09-10	30000	30000
1930	JOHN F. KING	1930-09-25	31000	31000
1931	JAMES G. WOOD	1931-10-10	32000	32000
1932	WILLIAM H. BROWN	1932-10-25	33000	33000
1933	EDWARD I. WHITE	1933-11-10	34000	34000
1934	MICHAEL J. GREEN	1934-11-25	35000	35000
1935	JOHN K. BLACK	1935-12-10	36000	36000
1936	JAMES L. GRAY	1936-12-25	37000	37000
1937	WILLIAM M. HARRIS	1937-01-10	38000	38000
1938	EDWARD N. KING	1938-01-25	39000	39000
1939	MICHAEL O. WOOD	1939-02-10	40000	40000
1940	JOHN P. BROWN	1940-02-25	41000	41000
1941	JAMES Q. WHITE	1941-03-10	42000	42000
1942	WILLIAM R. GREEN	1942-03-25	43000	43000
1943	EDWARD S. BLACK	1943-04-10	44000	44000
1944	MICHAEL T. GRAY	1944-04-25	45000	45000
1945	JOHN U. HARRIS	1945-05-10	46000	46000
1946	JAMES V. KING	1946-05-25	47000	47000
1947	WILLIAM W. WOOD	1947-06-10	48000	48000
1948	EDWARD X. BROWN	1948-06-25	49000	49000
1949	MICHAEL Y. WHITE	1949-07-10	50000	50000
1950	JOHN Z. GREEN	1950-07-25	51000	51000
1951	JAMES A. BLACK	1951-08-10	52000	52000
1952	WILLIAM B. GRAY	1952-08-25	53000	53000
1953	EDWARD C. HARRIS	1953-09-10	54000	54000
1954	MICHAEL D. KING	1954-09-25	55000	55000
1955	JOHN E. WOOD	1955-10-10	56000	56000
1956	JAMES F. BROWN	1956-10-25	57000	57000
1957	WILLIAM G. WHITE	1957-11-10	58000	58000
1958	EDWARD H. GREEN	1958-11-25	59000	59000
1959	MICHAEL I. BLACK	1959-12-10	60000	60000
1960	JOHN J. GRAY	1960-12-25		

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Agency: ASA

SOLE NUMBER	NAME OF DEPENDENT	SECRET ID	CO	DISC IN	ALLOWED	SP10
1	DICK JOSEPH					
2	IDA JULIA (WHITE M.)					
3	LARRY JOHN					
4	WILLIAM REXTER CAYOU					
5	WILLIAM HARRY					
6	CARNEY DAVID					
7	JOSEPH (HAINES)					
8	JOHN SARAH					
9	WILLIAM ALLEN					
10	ELIZABETH					
11	LAUREN MARY (WEST)					
12	WILLIAM CHARLES					
13	LEO					
14	JEANETTE (RICE)					
15	WILLIAM (HENRY)					
16	MARY (WRIGHT)					
17	MARGUERITE (KITTLE)					
18	JOHN					
19	MARY (WRIGHT)					
20	JOHN					
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BILLINGS AREA

ISSUE NUMBER	NAME OF DECEDENT	DECEDENT ID	PAID	PAID
1000	KILLED IN THE BUSH	394	1000	1000
1001	TURN TISS	395	1000	1000
1002	LOUIS STRINE	396	1000	1000
1003	TAKES THE BOW	397	1000	1000
1004	HOLY TREE	398	1000	1000
1005	CHARLES J BUCKMAN	399	1000	1000
1006	ATTACKS	400	1000	1000
1007	TAKES PRISONER WARRIOR	401	1000	1000
1008	THE GIRL	402	1000	1000
1009	ANY BLACK-PEAR WHITE	403	1000	1000
1010	MRS J BARRITY	404	1000	1000
1011	GRANTING WITNESS	405	1000	1000
1012	BEHIND THE HUNTER	406	1000	1000
1013	MARK FISH GUTS	407	1000	1000
1014	HINAM FACING	408	1000	1000
1015	AME WOMAN BUCK	409	1000	1000
1016	WIND CHIEF	410	1000	1000
1017	EL CITA TAO KILL	411	1000	1000
1018	GEORGE ROCK	412	1000	1000
1019	BEHIND THE HUNTER	413	1000	1000
1020	BEHIND THE HUNTER	414	1000	1000
1021	BEHIND THE HUNTER	415	1000	1000
1022	BEHIND THE HUNTER	416	1000	1000
1023	BEHIND THE HUNTER	417	1000	1000
1024	BEHIND THE HUNTER	418	1000	1000
1025	BEHIND THE HUNTER	419	1000	1000
1026	BEHIND THE HUNTER	420	1000	1000
1027	BEHIND THE HUNTER	421	1000	1000
1028	BEHIND THE HUNTER	422	1000	1000
1029	BEHIND THE HUNTER	423	1000	1000
1030	BEHIND THE HUNTER	424	1000	1000
1031	BEHIND THE HUNTER	425	1000	1000
1032	BEHIND THE HUNTER	426	1000	1000
1033	BEHIND THE HUNTER	427	1000	1000
1034	BEHIND THE HUNTER	428	1000	1000
1035	BEHIND THE HUNTER	429	1000	1000
1036	BEHIND THE HUNTER	430	1000	1000
1037	BEHIND THE HUNTER	431	1000	1000
1038	BEHIND THE HUNTER	432	1000	1000
1039	BEHIND THE HUNTER	433	1000	1000
1040	BEHIND THE HUNTER	434	1000	1000
1041	BEHIND THE HUNTER	435	1000	1000
1042	BEHIND THE HUNTER	436	1000	1000
1043	BEHIND THE HUNTER	437	1000	1000
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BILLINGS AREA

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1007	LENE RUNNING ISHER	106	1000	1000
1008	WILHELM	107	1000	1000
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1010	GEORGE COFF	109	1000	1000
1011	ANNIE P. SWELL	110	1000	1000
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1014	KILLIE ROUSLAS	113	1000	1000
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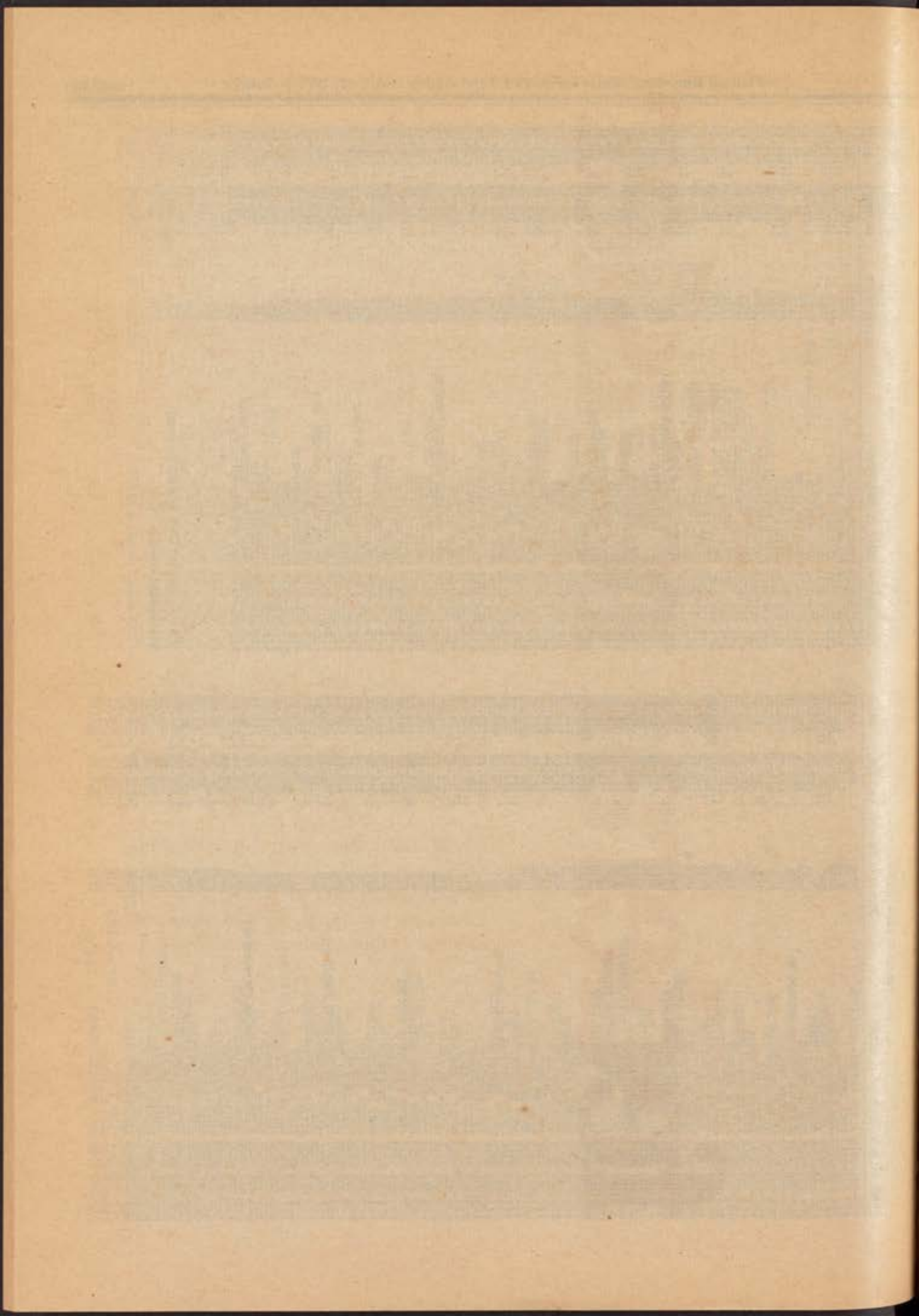
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42 CFR Parts 400 et al.

Wednesday
April 17, 1985

Part III

Department of Health and Human Services

Health Care Financing Administration

42 CFR Parts 400 et al.

Medicare and Medicaid Programs; Peer
Review Organizations; Final Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 400, 405, 412, 431, 433, 456, 460, 462, and 466

[HSQ-108-F]

Medicare and Medicaid Programs; Utilization and Quality Control Peer Review Organization (PRO): Assumption of Medicare Review Functions and Coordination With Medicaid

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This rule describes the review functions to be performed by a utilization and quality control peer review organization (PRO). It outlines the relationships that will be established among PROs, Medicare fiscal intermediaries and carriers, providers, practitioners, and beneficiaries when a PRO assumes its review responsibilities. It also describes the relationship that should exist between PROs and State Medicaid agencies that contract with PROs to perform review.

This rule implements portions of the following statutes:

- Peer Review Improvement Act of 1982 (Title I, Subtitle C of the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97-248)
- Social Security Amendments of 1983 (Pub. L. 98-21)
- Deficit Reduction Act of 1984 (Pub. L. 98-369).

EFFECTIVE DATE: These regulations are effective May 17, 1985 except for the following:

(1) Section 466.78(a) that specifies that each hospital have a written contract with a PRO is effective June 17, 1985.

(2) Sections 412.44, 431.630, 456.654, 466.70, 466.72, 466.74, 466.78, 466.80 and 466.94 contain information collection requirements with which the public is not required to comply until the Executive Office of Management and Budget (EOMB) approves these requirements. See section VI of the preamble for a discussion of information collection.

FOR FURTHER INFORMATION CONTACT: Mary Kay Terry, (301) 594-7910.

SUPPLEMENTARY INFORMATION:

I. Background

The Peer Review Improvement Act of 1982 (Title I, Subtitle C of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), Pub. L. 97-248) amended Part

B of Title XI of the Social Security Act (Act) by establishing the Utilization and Quality Control Peer Review Organization (PRO) program. This program, when fully implemented, will replace the existing Professional Standards Review Organization (PSRO) program. The responsibilities that PROs are assuming are similar to those now exercised by PSROs. PROs will review health care services funded under Title XVIII of the Act (Medicare) to determine whether those services are reasonable, medically necessary, furnished in the appropriate setting, and are of a quality which meets professionally recognized standards. Congress created the PRO program in order to redirect, simplify and enhance the cost-effectiveness and efficiency of the peer review of services reimbursed by Medicare.

The Social Security Amendments of 1983 established a prospective payment system for Medicare and amended section 1866(a)(1)(F) of the Act to specify that hospitals seeking reimbursement under the prospective payment system must enter into agreements with PROs by specified dates to review the following:

- The validity of diagnostic and procedural information supplied by the provider.
- The completeness, adequacy, and quality of care provided.
- The appropriateness of admissions and discharges.
- The appropriateness of care provided or proposed to be provided for which payment is sought on an "outlier" basis under the prospective payment system.

In addition, the amendments added section 1866(f)(2) of the Act to specify that the Secretary may deny payment or require the hospital to take corrective action if a PRO provides the Secretary with documentation that a hospital has circumvented the prospective payment system through unnecessary admissions or other practices.

The Deficit Reduction Act of 1984 (DRA) revised the provisions of the Social Security Amendments to require that all hospitals, not just those receiving payment under the prospective payment system, must maintain an agreement with a PRO. Effective November 15, 1984, all hospitals must have an agreement with a PRO as a condition of payment under Medicare.

The DRA amendments permit the Secretary to enter into contracts with entities or affiliated entities (other than self-insured employers) that directly or indirectly make payments to a provider or practitioner on or after November 15, 1984 if there is no other available entity. Section 1153(b)(2)(A) of the Act, as

amended, clarifies that the Secretary can contract with this type of entity if the entity does not have more than one member of the governing board being affiliated through management, ownership or common control with a health maintenance organization or competitive medical plan which is an "eligible organization" as defined in section 1876(b) of the Act.

In addition, Congress modified the restriction in section 1153(b)(3) of the Act. The Secretary may now contract with an organization that has no more than 20 percent of the members of its governing board affiliated with health care facilities or associations of facilities through management, ownership or common control.

In June of 1984, HCFA began awarding contracts to PROs. On July 17, 1984, we published a proposed rule (NPRM) which describes the PROs' review responsibilities and the PROs' relationships with other PROs, fiscal intermediaries, carriers, providers, beneficiaries, and State Medicaid agencies (49 FR 29026). Seventy-eight items of correspondence were received from the public. The provisions of the proposed rule, the comments we received and the changes that we made in response to those comments, as well as additional changes, are discussed below.

II. Provisions of the Proposed Regulations

A. PRO Implementation and Functions Under Medicare

The NPRM specified that HCFA would award contracts to PROs and further specified the procedures for notifying facilities to be reviewed by the PRO, State survey agencies, Medicare fiscal intermediaries and carriers, and the public about the PRO contract and the schedule for the implementation of review. The NPRM proposed general requirements for a PRO's assumption of review.

The NPRM included the specific dates by which health care facilities would be required to enter into an agreement with a PRO. As discussed in section I, above, these requirements have been revised by DRA.

The proposed regulations would have required PROs to negotiate memoranda of understanding with Medicare fiscal intermediaries and carriers that delineate the responsibilities of each party and provide for the exchange of data, notification of review determinations, and any other pertinent procedures. The NPRM proposed that any of the duties and functions of a PRO

for which a PRO has not assumed responsibility under its contract with HCFA must be performed in the manner and to the extent otherwise provided for under the Act.

The proposal specified that a PRO determination under 42 CFR Part 466 would be an initial determination that is final and binding unless it is reconsidered or revised in accordance with appeal procedures in 42 CFR Part 473, Subpart B. Final regulations for Part 473 are included elsewhere in this issue of the *Federal Register*.

The proposal described the correlation of the Title XI and Title XVIII functions of the PRO. A PRO's review determination with regard to reasonableness, medical necessity, and appropriateness of placement at an acute level of care would replace the utilization review activities required of health care institutions under sections 1861(e)(6), 1861(j)(8) and (j)(12), 1861(k) and 1865 of the Act. However, a PRO's review determination would not supersede HCFA's authority to enforce the coverage provisions of the statute. For example, although a service may have been medically necessary, it might be a service that is not covered under Medicare.

In order for a PRO to carry out its review functions, we proposed that a PRO be authorized to examine the operations and records of facilities that are pertinent to services provided to Medicare beneficiaries. A PRO would be permitted to examine the records of non-Medicare patients only if authorized to do so by the facility or practitioner or by HCFA under sections 1815 and 1833 of the Act.

We proposed that PRO review would differ from the current PSRO review with regard to requirements for the annotation of claims. PSROs were required to annotate all Medicare claims from health care facilities under their review to indicate whether the claims are approved for payment or denied. Because that procedure has been administratively cumbersome and ineffective, we proposed that PROs would not annotate every claim, but only those made for additional payment for an "outlier" case, those cases subject to preadmission review and those other claims that are denied.

The proposed regulations described the procedures a PRO must follow in making an initial denial determination. Before a PRO issues an initial denial determination, the proposed regulations would have required that the PRO afford the provider and the patient's attending physician (or other attending health care practitioner) the opportunity to discuss with the PRO physician advisor any

proposed denial determination and the bases for that determination. The proposal also described the content of the notice and the procedures for notifying the patient or the patient's representative, the attending physician, the Medicare fiscal intermediary or carrier, and the facility.

The proposed rule specified that the PRO review period is generally within one year of the date that the claim containing the item or service was submitted to the Medicare fiscal intermediary or carrier. A PRO determination could be reopened and revised by the PRO within four years of the date that the claim was submitted to the Medicare fiscal intermediary or carrier if additional information is received on the patient's condition or if an error had been made. The proposed rule stated that a PRO determination could be reopened or revised at any time if it was obtained through fraud or a similar abusive practice.

The NPRM proposed qualifications for the PRO reviewers. Generally, the services ordered or furnished by a doctor of medicine, osteopathy or dentistry may be denied only by another doctor of medicine, osteopathy or dentistry, respectively, who has active admitting privileges at one or more hospitals in the PRO area.

The NPRM specified that a PRO would be required to negotiate with HCFA concerning the use of national or regional norms for conducting review to achieve the objectives set forth in the PRO contract. A PRO would also be required to establish written criteria and standards to be used in the conduct of review.

The NPRM proposed that a PRO, in order to achieve economical and efficient review, would be required to coordinate activities (including the exchange of information) among Medicare fiscal intermediaries and carriers, other PROs, and other public or private review organizations as appropriate.

B. PRO Relationships With Medicaid

The NPRM specified that, as with PSRO requirements, when a State contracts with a PRO for medical or utilization review, the State must submit a plan amendment to the Regional Office for approval. The proposed rule specified that the State plan would assure that the contract with the PRO satisfied certain requirements. Again, as with current PSRO policy, a State that contracts with a PRO will be eligible for Federal financial participation (FFP) at 75 percent for funds expended for the performance of medical and utilization review under the contract. If a State

fails to make a satisfactory showing that it has an effective utilization control program (42 CFR 456.650), the reduction in FFP would not apply to facilities where either PSRO or PRO review is being conducted under an approved contract.

Under the proposed regulations, if a State contracts with a PRO, the medical and utilization requirements would be deemed to be met. However, the physician certification requirements and plan of care requirements would not be deemed met through an approved PRO contract. The proposed regulations added the requirement that the State agency, in its quarterly report that indicates that the State meets utilization requirements, must include facilities in which a PRO is performing review. As specified in the NPRM, the State agency's report for a quarter would have to include the dates a PRO was responsible for review in a facility for which a showing that the State met utilization requirements for recipients would otherwise have had to been made. More specific details of the proposal can be found in the document published on July 17.

III. Discussion of Comments

Note: We have made references within this preamble and regulations text to prospective payment regulations (previously §§ 405.470 through 405.477) that were redesignated under a new Part 412 on March 29, 1985 (50 FR 12740). References to these sections in the preamble of this document give both old and new citations for the benefit of the reader.

The majority of the comments we received on the proposed rule were from PSROs, hospitals, hospital associations, business groups and national medical organizations. The comments and our responses are set forth below and are grouped by subject area:

A. Statutory Provisions (§ 466.70)

Comment: One commenter noted that the proposed § 466.70(c) that would allow PROs to make payment determinations based on the completeness, adequacy and quality of care is not consistent with the PRO statute that only allows PROs to review services, not deny payment, based on these issues. Another commenter believed the regulations should not require the PRO to perform any duties in addition to those imposed by the statute.

Response: We agree with the first comment and have revised § 466.70(c), now redesignated as paragraph (d), to remove the reference to a PRO making a payment determination based on the completeness, adequacy and quality of care. We have deleted the reference to a

PRO making payment determinations based on quality contained in the definition of "Review responsibility" (§ 466.1). We have also removed the reference to a PRO making a payment determination based on changes resulting from DRG validations. As revised, the section provides that PROs will make payment determinations based on the reasonableness and medical necessity of services and the appropriateness of the acute care setting. Regarding the second comment, the Secretary has the authority, under section 1154(a)(8) of the Act, to issue regulations to implement the PRO program. We believe that all of the PRO activities required by these regulations are required by statute (sections 1154, 1866(a)(1)(F), 1866(f)(2) of the Act) and are necessary for an effective peer review program.

B. Notification of Designation and Implementation of Review (§ 466.72)

Comment: One commenter suggested that the PRO's notification that it is assuming review should include a list of the facilities to be under review. Another commenter believed that facilities should get a detailed explanation of the review process within 10 days of the signing of the PRO contract.

Response: Section 466.72(b)(2) of the proposed regulations specifies that the PRO will publish a notice in at least one local newspaper listing each facility to be under review. HCFA has also published newspaper notices announcing the award of individual PRO contracts. However, PROs are still required to issue a more detailed newspaper notice listing each facility under review and stating when and where their review plan is available for public inspection. Regarding the second comment, the regulations at § 466.72(b)(1) require that the hospital receive written notification of the date and manner by which the PRO will implement review. In addition, regulations at § 466.76 require a PRO to discuss the PRO's review process with the hospital. Also, the PRO's review plan is available at the PRO office for public inspection (§ 466.72(b)(2)). Therefore, we believe that the regulations contain adequate provisions to assure that hospitals are fully aware of the PRO's review procedures.

C. General Requirements for PROs (§ 466.74)

Comment: Fifteen commenters disagreed with the proposed regulations that specify that a PRO must not subcontract with a facility to conduct review activities that would affect

payment. The commenters stated that this prohibition is unfair, inefficient, ineffective and costly and recommended deleting this section and replacing it with criteria for delegation. A national medical organization believed the PRO should be allowed to subcontract with members of the medical staff who are not employees of the hospital and who do not have an ownership interest in the hospital.

Response: Although the PRO statute does not specifically prohibit PROs from subcontracting review responsibilities to facilities, we believe that subcontracting review responsibilities to hospitals would compromise the intent of Congress that there be no financial conflict of interest. Since 1981, Social Security Act legislation has reflected a clear departure from delegated hospital review. The Omnibus Reconciliation Act of 1981 removed the requirement that PSRO review be delegated and allowed PSROs discretion about whether or not to delegate review. TEFRA continued and strengthened this trend away from hospital delegation by limiting PRO subcontracting of review to those instances where the PRO finds that the provider will effectively and efficiently review itself. The Social Security Amendments of 1983 created the prospective payment system, where payment is based on a single review decision that affects payment for an entire hospital stay rather than multiple decisions that affect smaller units of payment over the course of a hospital stay. This, together with the Congressional concern expressed in the TEFRA legislation that there be no financial conflict of interest in PRO review, leads us to conclude that subcontracting any review that affects Medicare payment under the prospective payment system not be allowed. We also believe this prohibition should apply to non-PPS hospitals. The majority of PRO review is conducted retrospectively, after the patient has left the hospital. If a hospital were given the responsibility to conduct PRO review, it would therefore be asked to review and deny care, the cost of which it has already incurred. We consider this an extreme conflict of interest. Therefore, we are retaining the prohibition against subcontracting any review except quality review in this final rule.

Comment: Two commenters expressed concern about the requirement that the PRO make it contract primary to all other activities and believed this may interfere with PRO contracts for private review.

Response: Section 1154(b)(11) of the Act encourages PROs to engage in private review activities, but only to the extent feasible and appropriate. The intent of this provision of the regulations is that Medicare review not be compromised by any other PRO contract activities.

Comment: One commenter questioned whether PROs will compile statistics to determine a provider's favorable presumption status under section 1879 of the Act and whether the PRO will be required to notify the provider of its waiver status.

Response: We have included in § 466.74(e) provisions for circumstances when PROs are required to compile statistics to determine a provider's favorable presumption status using the criteria contained in § 405.332(b) and notify the provider of its status. Instructions concerning these compilations will be included in administrative guidelines.

Comment: One commenter believed the regulations should reflect the PRO's responsibility for confirming the accuracy of a hospital patient's discharge destination.

Response: We believe that the specific obligations of an individual PRO should be contained in that PRO's individual contract with HCFA rather than in regulations. Therefore, we are not revising the final rule as a result of this comment.

D. Cooperation with Health Care Facilities (§ 466.76)

Comment: Three commenters believed the 30 day timeframe for implementing review makes it very difficult for PROs to fully discuss their review plans with facilities. Another commenter requested that the regulations specify how a PRO must cooperate with facilities.

Response: We believe it is essential that a PRO begin its review activities as soon as possible after its contract is signed. In fact, we encouraged organizations that submitted proposals for PRO contracts to provide evidence that they had initiated discussions with facilities or associations of facilities in their area. Thus, we believe the 30 day timeframe is adequate for the discussion of review plans with facilities. Regarding the second comment, the individual agreements between PROs and facilities will detail the relationship between the two organizations.

E. Responsibilities of Health Care Facilities (§ 466.78)

Comment: A hospital representative questioned whether the hospital's Medicare payment would be in jeopardy

if the hospital did not have a contract with a PRO by October 1, 1984. The representative noted that there is no designated PRO for the area.

Response: As described in the preamble, the DRA amendments revised the date by which a hospital must have an agreement with a PRO. That date is now November 15, 1984. We note that there are now PROs in each geographic area.

Comments: Twenty-four commenters objected to the requirement in the proposed regulations (§ 466.78(b)(2)) that hospitals photocopy and deliver pertinent information to the PRO because it would increase hospitals' operating costs. The commenters further stated that the PRO should be required to conduct onsite reviews at the hospital whenever possible. The commenters also suggested that the regulations impose some limitations on the volume of material a PRO can request from a hospital and that they ensure the confidentiality of the records. Another commenter requested that the regulations specify that the PRO can request pre-admission records of tests in addition to the post-admission record.

Response: We believe it is important that PROs have adequate access to medical records to enable them to carry out required activities. This includes the right to request and receive copies as they deem necessary, including preadmission test records. In some cases, this will mean that the PRO will request hospitals to photocopy specific medical records and mail them to the PRO.

The prospective payment rates are computed according to the provisions of the law and are also based on the best available data at the time of computation.

Administrative costs are included in the Federal and hospital specific portions of prospective payments by virtue of their being incurred and reported by hospitals for the years that represent the data bases for the prospective payment system.

Prior to the use of PROs, review of inpatient hospital services was carried out either at the hospital or offsite. Offsite review sometimes required that the hospital mail patient records to Medicare fiscal intermediaries. These costs were subsumed in the hospital's administrative costs which in turn were reflected in Medicare cost reimbursement. Costs related to such activities are accounted for, in some measure, in the prospective payment base rates.

We also believe that the fiscal benefits of PRO review will compensate for any such increased costs. For

example, in many cases, PRO's preadmission review activities will protect hospitals from retrospective denials. Thus, there will be trade-offs between a hospital's cost of providing medical records to a PRO and the PRO's performance of review, that, in many cases, may assist hospitals in avoiding unnecessary expenditures.

We agree that the confidentiality of copied records is important and we plan to publish final regulations concerning PRO's protection of photocopied records as separate regulations.

Comment: One commenter questioned why the proposed rule did not contain provisions to satisfy the requirements under Section 1815(b) and 1861(w)(2) of the Act that specify that a hospital, as a condition of payment under Medicare, is obligated to pay a PRO an amount reasonably incurred by the PRO in conducting review activities at that hospital.

Response: Section 1153(c)(8) of the Act provides that reimbursement of PROs will be made in accordance with the terms of their contract with the Secretary. HCFA's policy in negotiating the terms of the PRO contracts has been that PROs will receive reimbursement directly from HCFA. This policy, which is in accordance with section 1153(c)(8) of the Act, eliminates the need for regulations that would specify that HCFA pay a hospital which in turn would pay a PRO for the conduct of review.

Comment: Many Commenters believed that hospitals should not be held financially liable for cases subject to preadmission review. The commenters believe that the PRO should be required to perform review in a timely manner and the beneficiary should be financially liable if the hospital notifies the beneficiary that services would not be covered. The commenters believed that the policy in the regulations is contrary to the limitation of liability provisions in section 1879 of the Act. Another commenter requested that we explain the difference between preadmission review and preadmission certification.

Response: We agree with the commenters that HCFA should not assign financial liability to providers in preadmission review cases in which both the patient and provider have knowledge that the proposed admission is medically unnecessary, unreasonable or inappropriate. Therefore, we have deleted this provision from § 466.78(b)(6) of the final rule. In accordance with section 1879(c) of the Act, if both the provider and beneficiary have knowledge that the proposed admission will not be covered by Medicare, HCFA

will not pay the bill and settlement will be between the hospital and the beneficiary. We are retaining the requirement that a facility agree to accept financial liability if (1) the facility has been notified by the PRO of the admission categories that are subject to preadmission review and certification; (2) the required PRO review has not been performed; (3) the facility admits the patient; and (4) subsequent PRO review finds the admission to be medically unnecessary, unreasonable or inappropriate. However, we are revising § 466.78(b)(6) to state that a hospital is not automatically liable if, in accordance with its agreement with the PRO, it makes a timely request for preadmission review and the PRO does not review the case. The agreements between the hospital and the PRO will contain specific details regarding the PRO preadmission review process including the timing of the request for PRO review and the PRO's response.

Regarding the request for clarification on the difference between preadmission review and preadmission certification, preadmission review is the process for determining, for payment purposes, the reasonableness, medical necessity and appropriateness of placement at an acute level of care. Preadmission certification is a favorable determination, transmitted to the hospital and the fiscal intermediary, approving of the patient's admission for payment purposes. We have included definitions of these two terms in § 466.1 of this final rule.

Comment: One State government suggested that the beneficiary should be informed of the reconsideration and appeals process at the time of admission. However, other commenters believed that we should eliminate the requirement that the beneficiary be informed by the hospital at the time of admission about PRO review because it would harm the patient and because the commenters believe it is the responsibility of the Government to inform the beneficiary.

Response: We believe it is important that Medicare beneficiaries be informed about the PRO review process at admission and the § 466.78 of these regulations adequately ensures that beneficiaries are aware of that process. We believe that the hospital can most effectively and efficiently provide this information to the beneficiary at the time of admission. Also, additional detailed information concerning PRO reconsiderations will be made available to beneficiaries by the PRO whenever a PRO denial determination is issued.

Comment: One commenter believed the regulations should specify that the hospital will provide space to the PRO for its review functions in accordance with other demands on the hospital for space.

Response: In their agreement, the PRO and the facility should work out an arrangement that provides the PRO with adequate space to perform its review functions while not placing a hardship on the facility.

F. Coordination with Medicare Fiscal Intermediaries and Carriers (§ 466.80)

Comment: Two commenters questioned whether the agreement between the PRO and the Medicare fiscal intermediaries or carriers has to be approved by HCFA before review can begin because this could delay implementation of review. The commenters believed that we should establish timeframes for submission of the agreements to HCFA and for approval by HCFA.

Response: The regulations require that the agreements must be approved by HCFA before the PRO begins to make review determinations. Because PRO contracts will be signed at different times, each PRO contract will contain a timeframe that is adequate for the PRO and the fiscal intermediary or carrier to reach an agreement. Therefore, we are retaining this provision in § 466.80(c) of the final regulations. We do not believe that more rigid timeframes would necessarily facilitate the negotiation process. Also, every organization that submitted a proposal for a PRO contract was asked to provide a draft agreement and to verify that it had initiated discussions with the appropriate fiscal intermediary. It is our intention that all PRO contracts be awarded in sufficient time for agreements to be signed by the November 15th deadline.

G. Continuation of Functions (§ 466.82)

Comment: One commenter asked who is responsible for certain review activities once a PRO contract is effective. Specifically, the commenter asked who is responsible for review activities not initiated or not completed by the fiscal intermediary or former PSRO for Medicare hospital admissions occurring before the effective date of the PRO contract. Another commenter believed that § 466.82 dealing with the continuation of functions is unnecessary because, as of November 15, all hospitals will have review contracts with PROs.

Response: The pro is responsible for all review activities specified in its contract with HCFA. In most cases, these contracts include the completion

of any PSRO activity. We believe that § 466.82 is still necessary because fiscal intermediaries must, in the unlikely event that a PRO contract terminates before a new contract is signed, be responsible for these review functions. The fiscal intermediary will also be responsible for any review function that the PRO has not yet assumed, but which it may assume at some future time.

Comment: Two commenters believed that the fiscal intermediaries should not be making determinations on medical necessity, reasonableness, or level of care. Another commenter believed that the PRO should use norms of care, not HCFA coverage policy, in making review determinations. One commenter believed the regulations appear to state that PRO review determinations are final and binding, but believed that all cases should be subject to appeal.

Response: In responses for the first comment, the regulations at § 466.85 provide that, if a PRO has assumed review responsibility, the PRO, in fact, is responsible for making determinations based on medical necessity, reasonableness and level of care. However, the fiscal intermediary will continue to make coverage determinations on other bases, including whether the service is a statutorily excluded service. It is bound, for payment purposes, by a PRO determination with respect to a medical necessity issue. Regarding the last comment, PRO initial denial determinations are final and binding, subject to appeal under 42 CFR Part 473. Final regulations for Part 473 are published elsewhere in this issue of the *Federal Register*.

Comment: One commenter believed that the regulations should state that the PRO's determination about whether outpatient or other inpatient care is appropriate must be consistent with medical care in the community and must take into consideration the availability and accessibility of care to the patient.

Response: Although we basically agree with the commenters, we do not believe the regulations should address these specific issues. In developing their review criteria, PROs must take into consideration the appropriate medical care in the community.

Comment: Two commenters objected to the need for hospitals to reinstate physician certification. The commenters believed that this will be an administrative burden on hospitals.

Response: The PRO statute does not contain the provision included in the PSRO statute at 1156(d)(1)(B) of the Act that permitted the use of PSRO review to meet the physician certification requirements of the Act. Therefore, to be

consistent with the PRO statute, we are retaining this provision for the final rule.

H. PRO Access to Non-Medicare Patient Records (§ 466.88)

Comment: Thirty-five commenters argued that the proposed regulations regarding a PRO's access to the medical records of non-Medicare patients (§ 466.88(b)) are contrary to the provisions of the statute. Section 1866(a)(1)(E) of the Act requires a hospital to release these records to a PRO for its conduct of review under a contract with a private or public agency. As written, the proposed regulations would allow a hospital to deny the PRO access to the medical records of non-Medicare patients. One commenter also questioned whether the working aged are considered Medicare patients when Medicare is not the primary payor.

Response: We agree with the commenters and are revising § 466.88(b) to provide that a PRO may obtain non-Medicare patient records relating to review performed under a non-Medicare PRO contract, if authorized by the patient under State law. This includes records of the working aged and beneficiaries who are dually entitled under Titles XVIII and XIX. However, when these beneficiaries are receiving Medicare services, all Medicare review rules apply. A PRO may also obtain non-Medicare patient records in accordance with its quality review responsibilities under the Act, only if authorized by the institution or practitioner.

Quality review is an integral and essential element of the PRO statute. Section 1154(a)(1)(B) of the Act specifies that any PRO must (in accordance with its contract with the Secretary) perform review to determine whether the quality of care provided to Medicare beneficiaries meets professionally recognized standards of health care. This PRO requirement represents the continuation of a peer review function mandated by the Medicare statute over the past ten years. In section 1154(a)(6), the Congress provides the same process for PROs as it had for earlier Medicare peer review for prescribing the way in which quality review would be performed by PROs, namely, regulations of the Secretary. Furthermore, the provisions of section 1154(a)(7)(D) and (a)(9) direct PROs, in a way similar to earlier peer review organizations, to inspect facilities and collect information necessary to carry out PRO review functions, including quality review. Section 1866(a)(1)(E) imposes a similar obligation on Medicare providers to release patient care data to PROs for

review purposes including the conduct of Medicare quality review. Taken together, these provisions give statutory authority to PROs to conduct quality review in the same manner as conducted by previous Medicare peer review organizations.

The quality review process consists of screening patient care information to identify and verify quality problems in addition to conducting quality review studies. A quality review study is an assessment conducted by or for a PRO of a patient care problem for the purpose of improving the patient care of some or all providers or practitioners in the PRO area through peer analysis, intervention, and resolution of the problem and follow-up.

While the problem studied must affect Medicare patients, it usually affects other patients as well, especially in the context of acute inpatient care. This is because quality problems relate to the way in which care is delivered (i.e., the behavior of a provider or practitioner). In some of these cases, a problem can be adequately addressed for Medicare patients only by addressing the problem for all patients in an acute care setting.

This means that in some quality review studies a PRO must review both Medicare and non-Medicare patient records in order to resolve the problem for Medicare patients. For example, a Medicare quality review study may seek to analyze and resolve a problem in the use of prophylactic antibiotics in certain operations which, when not used, increase the rate of infections post-operatively. However, for individual providers or specific practitioners, the frequency of certain operations for Medicare patients may be too low to draw reliable conclusions about the proper use of these antibiotics by that practitioner or in that provider on a timely basis (i.e., it may take a year of data collection for Medicare patients only). In contrast, the frequency for these operations performed on all patients may be adequate to permit timely and reliable assessment of the problem (i.e., within one to three months) and permit more rapid problem resolution for Medicare patients.

Also, physician and hospital-wide studies encourage general resolution of problems through the alteration of area practice patterns. This benefits both Medicare and non-Medicare patients and assures more substantive and longer lasting improvement in a problem than could have been achieved by focusing only on Medicare patients.

I. Examination of the Operation and Records of Facilities (§ 466.88)

Comment: Several commenters believed that PROs should only examine hospital information and charges for outlier cases and those other items required by law. Other commenters felt the language in § 466.88 is vague and requires PROs to duplicate fiscal intermediary efforts. Other commenters requested that we specify what aspects of a hospital's operation a PRO can examine and that PROs should be required to submit results of inspections in writing to the facility. Another commenter noted that the proposed regulations that allow a PRO to examine a hospital's operation in order to determine a hospital's capability to perform review should refer specifically to quality review, as this is the only review that may be delegated to a hospital. Another commenter questioned whether the facility may have access to PRO records.

Response: We believe that the regulations are consistent with the statute, which gives PROs the authority to inspect facilities and records of health care facilities and providers for the purpose of carrying out their responsibilities as specified in the Act. PROs may require hospital charge information for many types of review, such as ancillary services or quality review of inappropriate utilization. We have, however, deleted the reference to cost information from § 466.88(a) because we do not anticipate a need by PROs for this information in carrying out their statutory and contractual responsibilities. PRO review does not duplicate fiscal intermediary review because the functions of each are coordinated as described in § 466.88 of these regulations. For example, only PROs will make determinations based on medical necessity, reasonableness and appropriateness of inpatient care. Only fiscal intermediaries will make coverage determinations on services excluded by statute. The results of PRO review will be made known to hospitals in accordance with provisions that will be included in 42 CFR Part 476. We agree with the comment that the reference to the capability of the facility to perform review should refer specifically to quality review, and we have revised § 466.88(a)(3) accordingly.

J. Lack of Cooperation by a Health Care Facility or Practitioner (§ 466.90)

Comment: Some commenters questioned whether, if a PRO denies a claim because the hospital did not submit requested information, the hospital can then submit the information

and request a reconsideration. Two commenters believed that the proposed regulations at § 466.90 are vague and requested definitions and clarifications.

Response: If a PRO denies a claim because a hospital did not submit requested information, the hospital may request a reopening of the case after submitting the requested information in accordance with regulations in 42 CFR Part 473. Final regulations for Part 473 are also published in this issue of the **Federal Register**. We are not making any significant changes to § 466.90 because we believe that the terms used in the section have been defined or explained elsewhere in the text of the regulations.

K. Opportunity to Discuss Proposed Initial Denial Determination (§ 466.93)

Comment: Seven commenters recommended that we revise the proposed requirement that a PRO afford an opportunity for the provider and physician (or other attending health care practitioner) to discuss a proposed initial denial determination with the PRO physician advisor. The commenters believed that this requirement should not apply when a retrospective review is performed by the PRO after the patient is discharged from the hospital because it would result in an increased administrative burden to the PRO and would be impossible to implement. One commenter also suggested that if retrospective review is performed, an exit interview should be furnished to the hospital upon request. Another commenter questioned whether there is a need for both the provider and practitioner to discuss the proposed denial.

Response: Section 1154(a)(3) of the Act requires the PRO to afford an opportunity to the provider and practitioner to discuss any initial denial determination. In addition, our proposed rule would increase review flexibility and reduce the costs of issuing unnecessary denials or conducting reconsiderations by providing an opportunity for discussion to both provider and practitioner prior to issuing a denial. We believe this is a more efficient and less cumbersome procedure than exit interviews or retrospective denials alone.

Comment: A hospital association suggested that the PRO should be required to notify the provider and the physician of the proposed denial within 24 hours of the denial decision. Another commenter recommended that the provider and physician be given 24-hours to respond to the PRO's notification.

Response: We do not believe it would be appropriate for the regulations to require a 24-hour limit for notification of the provider and practitioner or for their response. However, in their individual agreements with PROs, hospitals may wish to negotiate these types of provisions.

L. Notice of PRO Initial Denial Determination (§ 466.94)

Comment: Several commenters objected to the proposed requirements that the content of a PRO's notification to a patient of an initial denial determination be the same as that used to notify the practitioner or provider. The commenter argued that, since in most cases the patient would not be liable for payment, it is inappropriate to include the same amount of detail that would be given to the practitioner or provider. Another commenter believed the notice to the patient should only be issued after all local appeals are completed.

Response: Section 1154(a)(3) of the Act specifically requires that the PRO promptly notify the practitioner, provider, patient and payment agency of the denial decision. The Act does not specify that the patient should receive a less detailed notice than the other parties. Therefore, we believe it appropriate that the patient be fully informed and receive the same notice as the other parties and at the same time. Also, in order to appeal a denial determination, a patient must receive timely notice of the denial.

Comment: Three commenters believed that the regulations should contain the specific requirements for the content and format of the denial notice in order to ensure that the notices are understandable, complete, written in plain English, and clearly represent the nature of the PRO's decision. The commenters believed the PRO and the hospital should negotiate the wording of the notice.

Response: We believe the wording of the denial notice is the responsibility of the PRO and should not be subject to negotiation with the hospital. We do agree with the commenters that the regulations should contain specific requirements for the content of the denial notices and we have included appropriate language in § 466.94 of the final rule. Also, we will be monitoring PRO denial notices to ensure that they can be understood by all parties and do not cause unnecessarily adverse reactions among the recipients.

Comment: One commenter believed the regulations should not limit when a patient's representative can be involved.

Response: We believe the regulations adequately provide for the protection of the patient and the inclusion of a patient representative, when appropriate.

Comment: One commenter pointed out that since Saturday and Sunday are not always working days, it might take three days for the delivery of a denial notice. The commenter also questioned what "prompt written notice" to the fiscal intermediary would be and suggested it be the same timeframe as the issuance of the notice to the other parties.

Response: We agree with the commenter and have revised the proposed § 466.94(c) (this is § 466.94(a)(2) in the final rule) to specify that the time periods for delivery of the notices are all in terms of "working" days, rather than calendar days. We have also revised the timeframe for the notice to the fiscal intermediary to be the same as the notice to the other parties. We have also added timeframes for the notice to the practitioner and provider regarding changes as a result of a PRO's DRG validation.

M. Review Period and Reopening of Denial Determinations (§ 466.96)

Comment: Three commenters suggested that a PRO should not have more than 120 days to deny payment, rather than the one year generally specified in the regulations. Another commenter suggested that the proposed § 466.96(b) that would allow denial determinations to be made within four years of the date of the claim for service should be deleted because all reviews should be completed within one year.

Response: We believe the timeframes specified in the regulations are appropriate because they are similar to other Medicare review time limits at § 405.750(b)(2). To assure the efficiency of the review process, we are limiting to one year the time period during which a PRO may on its own make or reopen an initial denial determination or a change as a result of a DRG validation. In addition, we are revising § 466.96 to allow up to four years for an initial determination change or a change as a result of a DRG validation to be made, reconsidered or revised as described in the regulations. We have deleted the proposed requirement that these actions first be approved by the HCFA Regional Administrator.

N. Reviewer Qualifications and Participation (§ 466.98)

Comment: Several commenters believed that doctors of medicine (M.D.s) and osteopathy (D.O.s) should be allowed to review each others' care. Other commenters suggested that specialists be able to request review by

another specialist in the same discipline. Another commenter was concerned that only appropriately qualified medical record personnel perform DRG validation. Another commenter believed the regulations should prohibit a person from performing review who is connected with a facility that is in competition with the facility under review. Also, one commenter suggested that any physician who receives compensation from a hospital should be prohibited from performing review. Another commenter believed the role of the non-physician in the review process should be detailed in the regulations.

Response: We believe it is the intent of the statute and the most effective method of peer review, for M.D.s to review M.D.s, and D.O.s to review D.O.s. We have, however, made an exception to this rule when the appropriate peer is not available to perform the review. Although the suggestions of the commenters regarding review by specialists may have merit, we do not believe these requirements should be included in regulations. However, we have revised the regulations to require that changes as a result of DRG validations be made by a physician and that individuals with training and experience in ICD-9-CM coding must review the technical coding issues. Additionally, the final regulations in Part 473 published elsewhere in this issue of the Federal Register do require that the reconsideration reviewer be a professional peer of the practitioner under review. Regarding the next two comments, we do not believe it is appropriate to include these limitations on the qualifications of reviewers. We believe that the regulations adequately protect against a conflict of interest and that further restrictions are not necessary. Regarding the last comment, we believe that § 466.102 adequately addresses the role of non-physicians in the review process.

O. Use of Norms and Criteria (§ 466.100)

Comment: Several commenters believed that the regulations do not reflect the Congressional intent that PROs use local norms, taking into consideration national norms. Other commenters expressed concern that the PRO may be discriminatory in applying different criteria to different locations and facilities. Other commenters suggested that the PRO be required to describe to the hospital how it arrived at the numbers of procedures selected for preadmission review. Another commenter believed the PRO should be required to make available to the

hospital the criteria, norms and standards used in review. Another commenter suggested that the regulations specify the body of knowledge to be used to determine national norms.

Response: Section 1153(c)(7) requires that negotiated PRO contracts include specifications for use of regional or national norms for setting contract objectives and performing review functions. Norms are statistical values used to establish standards of care and PRO objectives. In contrast to these norms, section 1154(a)(6) of the Act specifies that in their review PROs must use professionally developed norms based upon typical patterns of practice within the PRO area. These are in fact review criteria which are developed by each PRO. Criteria may reflect special circumstances in the PRO area. Regarding the last comment, the PRO agreement with the hospital should contain the specifics for exchange of data, including review criteria.

P. Coordination of Activities

Comment: One commenter suggested that PRO's should be allowed to exchange only aggregate data and that the regulations should preclude disclosure and redisclosure of unauthorized information. Another commenter suggested that the information should be exchanged only with those who have a financial interest in the case.

Response: The exchange of data is governed by the PROs review responsibilities as set forth in section 1154 of the Act. In some cases, the data may be aggregated, but in other cases may contain more detailed information. Regulations governing the acquisition, disclosure and redisclosure of PRO data will be contained in 42 CFR Part 476 and will be published in the Federal Register.

Q. HMOs

Comment: Two commenters suggested that HMO patients be exempted from review because the HMO receives a prospective payment and the HMO already has an incentive to provide efficient care.

Response: The statute does not exclude HMO patients from PRO medical review. We believe that PRO review is important because the quality of care is a critical issue for HMO and other patients treated on a capitated payment basis. Therefore, we are not revising the final rule to exempt HMO patients from PRO review.

R. Hospital Issued Denial Notice

Comment: One commenter suggested that the regulations provide that a patient be entitled to an expedited review of the hospital's denial notice and that the hospital be required to notify the patient of appeal rights before the notice is issued. Another commenter questioned whether the provisions of § 466.78(b)(4) are in conflict with a hospital's right to issue denials because that section would require that hospitals issue denials only in accordance with their agreement with the PRO.

Response: Regulations concerning the timing and review of hospital-issued denial notices are contained in § 412.42(c)(3) (previously § 405.472(b)(1)(iii)(C)). Therefore, we are revising § 466.78(b)(4) to specify that when a hospital has issued a written determination in accordance with § 412.42(c)(3) that a beneficiary no longer requires inpatient hospital care, it must submit a copy of its determination to the PRO within 3 working days.

S. Impact

Comment: Four commenters believed that the impact analysis that appeared in the NPRM was incorrect in stating that the regulations will not have an annual effect of \$100 million.

Response: In the Impact Analysis of this final rule, we have included a voluntary regulatory impact and regulatory flexibility analysis. The analysis acknowledges that a substantial number of facilities, practitioners and beneficiaries will be affected by implementing the PRO program. However, for the following reasons, we believe that the annual impact will not be significant, nor will it meet the \$100 million threshold criterion. The reasons we cite are: (1) The primary impact results from Congressional intent and from the individual PRO contracts; (2) the incremental differences between most PRO and previous peer review activities are not significant; and (3) the effect of PRO activities may not be the primary cause of these impacts. The influence of other factors like the prospective payment system and other third-party payor review efforts to reduce unnecessary admissions and procedures, may have a greater impact on costs than the effects of the PRO activity.

T. Objectives

Comment: Several commenters expressed concern that the objectives are, in fact, quotas and that they could have a negative impact on quality. Another commenter was concerned that setting unrealistic objectives will erode

PRO credibility with the medical community. Some commenters were concerned that PROs would be held accountable for their contract objectives even though circumstances beyond their control prevented them from accomplishing their objectives.

Response: While PROs have negotiated specific contract objectives in accordance with requirements contained in section 1153(c)(7) of the Act, these objectives are targets, or quotas. We recognize that there are circumstances under which the objectives may need to be modified. For example, quality objectives would be modified if data developed during the course of the contract demonstrates that the problem targeted is not as severe as previously thought, or if the PRO identifies a different problem of greater importance. Utilization objectives would be modified as a result of demographic shifts (for example, an influx of Medicare beneficiaries into the PRO service area), the effects of new technology, etc.

This approach will allow us to be responsive should circumstances for the PRO change significantly, while also retaining the accountability and performance incentives built into a specified, outcome-oriented contract. In addition, we will periodically review all PRO required review activities to evaluate their appropriateness and cost effectiveness.

U. Medicaid Provisions

Comment: One commenter objected to the provision that reimburses a State at 75 percent when they contract with a PRO to perform medical and utilization review, but only 50 percent when they contract with any other organization. Another commenter questioned what the reimbursement will be for those States with superior utilization review systems waivers granted under 42 CFR 456.505, currently reimbursed at 75 percent.

Response: Sections 1903(a)(2) and (7) of the Act provide that States will be reimbursed at 75 percent for the cost of utilization review activities performed by a PRO under contract with a State or by State employees but only 50 percent for review performed by others under a contract. Under section 1903(a)(2) of the Act, States that have been granted superior systems waivers to perform utilization review activities can be reimbursed at 75 percent for those activities performed by State employees.

Comment: One commenter pointed out that we had an incorrect cross-reference in § 431.630(b).

Response: We agree and have corrected the cross-reference in the regulations text.

V. Definitions

Comment: One commenter pointed out that the definition of grace days conflicts with 42 CFR 405.472, which requires 2 grace days after termination of benefits.

Response: Grace days as used in our proposed definition at 42 CFR 466.1 and as defined in 42 CFR 405.330 refer to additional days of Medicare payment (not more than 2 days) that a PRO or fiscal intermediary may, at its discretion, provide to arrange for post discharge care. In contrast, the provisions at § 412.42(c) [previously § 405.472(b)] describe when a hospital may begin to charge a beneficiary for services provided during a stay otherwise covered by a DRG payment. These provisions do not provide for additional Medicare payment but do specify when a hospital may charge the beneficiary (i.e., the day after the second day after the issuance of a hospital denial notice). Therefore, we believe our explanation of grace days is appropriate. We note that we are deleting the definition of grace days that was in our proposed § 466.1 because we did not specifically refer to grace days elsewhere in the proposed rule. We have, however, included our explanation of the term at § 466.70(d). We also note that we are changing our explanation of grace days. We previously stated that PROs may grant grace days for the purpose of arranging for post discharge care when neither the provider nor the patient knew or could reasonably be expected to have known that Medicare payment for the service would not be made. In accordance with section 1154(a)(2)(B) of the Act, we have revised our explanation to refer only to the provider's lack of knowledge regarding coverage of services.

Comment: Two commenters believed that the definition of "active staff privileges" is unduly restrictive. Many practitioners, such as psychologists, have privileges to practice independently in the hospital, but do not have admitting privileges. One commenter suggested that the definition include practitioners who are authorized to perform diagnostic services in a facility on a regular basis.

Response: The PRO program is a medical peer review program. To achieve true peer review, we believe it is essential that any PRO reviewing physician be actively practicing his or her profession which includes admitting patients to acute care hospitals.

Comment: One commenter questioned why the definitions of "length of stay norms" and "length of stay projections" only refer to PSROs. The commenter believes these definitions should also apply to PRO outlier reviews.

Response: We have revised these definitions to apply to both PSROs and PROs. PROs will be performing length-of-stay review in both non-PPs and specialty hospitals.

Comment: One commenter suggested that the definition of "quality review study" should include the element of follow-up to the problems identified to ensure that they are corrected.

Response: We agree with the commenter, and have added the element of follow-up to the definition of "quality review study".

Comment: One commenter suggested that the regulations should include a definition of "criteria".

Response: The definition of "criteria" is already contained in § 466.1. The definition did not appear in the July 17th Federal Register publication because the definition is unchanged from that contained in current regulations.

IV. Final Regulations

Based on the comments received and other considerations, we are making the following changes to the proposed rule. We also have made technical changes to the proposed regulations to correct drafting errors and to simplify and clarify certain sections.

A. Statutory Provisions

In the proposed § 466.70(a), we are replacing the reference to specific legislation with the important statutory cites relating to PRO review responsibilities. We are revising the proposed § 466.70(b) that is redesignated as § 466.70(c) to include the requirement that PROs make determinations as to whether a hospital has misrepresented admission or discharge information or has unnecessarily admitted patients to a hospital. This conforms to existing regulations at § 412.48 [previously § 405.472(e)]. We are revising the proposed § 466.70(c) that is redesignated as § 466.70(d) to conform to section 1154 of the Act that specifies that a PRO cannot make payment determinations based on the quality of care. Additionally, in § 466.70(d), we are specifying that PROs may grant grace days. In accordance with section 1154(a)(2)(B) of the Act, we refer only to the provider's (and not the patient's) lack of knowledge regarding coverage of services.

B. General Requirements for the Assumption of Review

We are revising § 466.74(e) to require that PROs compile statistics to determine a provider's favorable presumption status and notify the provider of its status.

C. Responsibilities of Health Care Facilities

We are revising § 466.78(a) to conform to section 1866(a)(1)(F) of the Act as revised by the DRA to require that effective November 15, 1984, all hospitals seeking payment under Medicare must maintain an agreement with a PRO. We also are specifying that the agreement must be in writing. In order to allow time for these agreements to be established, we are specifying that this provision is effective June 17, 1985 rather than May 17, 1985 which is the effective date for the other provisions of this rule.

We are revising the proposed § 466.78(b) to specify that when a health care facility has issued a written determination in accordance with regulations at § 412.42(c)(3) [previously § 405.472(b)(1)(iii)(C)], it must submit a copy of its determination to the PRO within 3 working days. We are revising § 466.78(b)(5) that requires a facility to assure that each case subject to preadmission review has been approved by the PRO before admission. We are adding the alternative that the facility assure that a timely request for the PRO preadmission review has been made. In § 466.78(b)(6), we have deleted the proposed provisions that would have assigned financial liability to a hospital in cases in which both the patient and the provider had knowledge that a proposed admission was medically unnecessary, unreasonable or inappropriate. We are also adding a provision to state that a facility is not automatically liable if, in accordance with its agreement with the PRO, it makes a timely request for preadmission review and the PRO does not review the case. This type of case is subject to retrospective prepayment review.

D. Coordination with Medicare Fiscal Intermediaries and Carriers

For consistency, we are changing the references to an "MOU" in this section to "agreement". We are also adding language in § 466.80(b) to provide that the PRO inform intermediaries and carriers of changes that result from DRG validations and the revisions that result from the review of these changes. In § 466.80(e) that specifies that an intermediary will not make payment unit it receives notice that the PRO has

approved the admission, we are specifying that the PRO's approval will be after a preadmission or retrospective review.

E. Initial Denial Determinations

We are revising the proposed § 466.83 to include a clarification of what constitutes an initial denial determination. We are redesignating the proposed § 466.84 as § 466.85 and adding a new § 466.84 to explain that changes as a result of DRG validations may be reviewed by a PRO in accordance with 42 CFR Part 473. The newly designated § 466.85 is revised to specify that both PRO initial denial determinations and changes as a result of DRG validations are final and binding unless reconsidered, reviewed and revised in accordance with Part 473. We note that we have made changes in several other sections of the proposed regulations in order to include the PRO review activity regarding DRG validation.

F. Correlation of Functions

We are revising the format of the proposed § 466.86 for clarity. In some cases, we are changing the citations of the statute to the appropriate citations of the regulations. In § 466.86(a)(1)(iv), we are clarifying that PRO determinations regarding the appropriateness of the setting are conclusive for payment purposes. Additionally, we are revising and adding the proposed § 466.92(b) to § 466.86 of the final rule because both sections concern coverage determinations.

G. Examination of the Operation and Records of Facilities

We are revising § 466.88(a) and (c) to delete the requirement that facilities permit a PRO to examine their cost information. We are revising § 466.88(a)(1) that lists certain PRO functions for which a facility must provide the PRO access to its records and operations. We are specifying that PRO access is not limited to the functions listed. We also are revising the proposed § 466.88(a)(3) to specify that a facility must permit a PRO to examine its operation and records to evaluate the facility's capability to perform quality review. We are revising the proposed § 466.88(b) that previously permitted a PRO to have access to non-Medicare records only if authorized by a facility or practitioner. We are now stating that a PRO may examine these records if: (1) The records relate to review performed under a non-Medicare contract and if authorized by the patient in accordance with State law, or (2) necessary to

perform quality review functions and if authorized by the facility or practitioner.

H. General Requirements for PRO Review

We are deleting the proposed § 466.92(a) regarding certain coverage issues that are involved in making a determination of the appropriateness of care. We are deleting this provision because the regulations contain a similar statement in § 466.86(c) that the Medicare fiscal intermediaries and carriers are not precluded from applying Medicare coverage policy rules. Additionally, we are adding the language contained in the proposed § 466.92(b) to § 466.86(c) since these sections are related and should be grouped together.

I. Notice of PRO Initial Denial Determination or Changes as a Result of a DRG Validation

We are revising the format of the proposed § 466.94 for clarity. In § 466.94(a) of this final rule, we discuss specific requirements for initial denial determination notices, including the parties to be notified and the timing of the notice. We are adding a requirement to this paragraph that PROs must document that the patient and facility receive notice of the initial denial determination in cases of preadmission review. We are clarifying that the time periods for the delivery of the notices are in terms of "working" days.

Also, we are adding a new paragraph (b) to include specific requirements for notice of changes as a result of DRG validations. We are including in this final rule at § 466.94(c) a requirement that PRO determination and DRG change notices be understandable and written in plain English.

Finally, we are revising § 466.94(d) and (e) to require that PROs notify payors of changes as a result of DRG validations and to expand the record retention requirements to include a record of these changes.

J. Review Period and Reopening of Determinations

We are revising the proposed § 466.96 for clarity and to include requirements for the review and reopening of changes as a result of DRG validations. We are limiting the time period to one year in which a PRO may make an initial denial determination or a change resulting from a DRG validation on its own. We are deleting the requirement in the proposed § 466.96(b) that denial determinations made after one year but within 4 years be approved by the HCFA Regional Administrator. Instead, we are requiring that HCFA evaluate on a case-by-case

basis whether the PRO will be permitted to make an initial denial determination or change as a result of DRG validation after the one year review period but within 4 years. In evaluating whether the PRO may make an initial denial determination or change DRGs, within the 4 year period, HCFA will assess whether the potential benefits of the review activity are justified in terms of the administrative burden on HCFA. We are also adding a provision stating that if there is an error on the face of the evidence, an initial denial determination or change as a result of a DRG validation may be reopened after one year but within four years. We inadvertently omitted this in our proposed rule but had included it in the proposed regulations for 42 CFR Part 473 concerning PRO reconsiderations and appeals (49 FR 29041). We note that the provision allowing PROs to review, at anytime, claims involving fraud or abuse, includes claims that may not have been previously reviewed by the PRO or those that were reviewed but were not denied by the PRO.

K. Reviewer Qualification and Participation

In § 466.98, we are adding a new paragraph (c) and redesignating the proposed paragraph (c) as (d). The new provision clarifies that decisions about procedural and diagnostic information must be made by physicians. However, (OIG) technical coding issues must be reviewed by individuals with training and experience in ICD-9-CM coding. This change conforms to regulations in Part 473 that are published elsewhere in this issue of the Federal Register.

L. Definitions

We are making several changes to the definitions located at § 466.1 as follows:

- We are deleting the proposed definition of "annotation" because we had previously deleted the reference to this term in the regulations text.
- We are revising and moving the definition of "area" to § 400.200 that contains definitions for terms used throughout 42 CFR Chapter IV.
- We are deleting the reference to PSROs in the definition of "concurrent review" so that the definition applies to both PSROs and PROs.
- We are deleting the definition of "denial" because we have added further explanations of denials in §§ 466.84 and 466.85.
- We are revising the definition of "DRG" for clarity.
- We are deleting the definition of "grace days" because we did not specifically refer to grace days in the

proposed rule. We note, however, that we are adding a provision at § 466.70(d) that states that PROs may grant grace days and explain the term.

- We are deleting the definition of "health care service" because this term is self-explanatory.

- We are deleting the reference to PSROs in the definitions of "length-of-stay norms" and "length-of-stay projections" so that the definitions apply to both PSROs and PROs.

- We are revising the definition of "non-facility organization" for purposes of clarity and to specify that it does not include entities that are owned by one or more associations of health care facilities. This requirement is specified in section 1153(b)(3) of the Act and we inadvertently omitted it from our proposal.

- We are adding the definitions of "preadmission certification", "preadmission review" and "preprocedure review".

- We are deleting the definition of "PRO" because it appears in § 400.200 that contains definitions that are used throughout 42 CFR Chapter IV.

- We are deleting the proposed definition of "provider" because this term has been defined in § 400.202. Since the definition we proposed included suppliers, we are making specific reference to suppliers where applicable in the regulations text.

- We are revising the definition of "quality review study" to limit it to the quality review studies conducted by or for a PRO for a patient care problem. We are also including an element of follow-up to the definition.

- We are revising the definition of "review responsibility" to delete an incorrect reference to a PRO's payment determination based on the quality of health care. We are also adding language to clarify that PRO decisions regarding changes as a result of DRG validations are conclusive.

- We are deleting the definition of "Utilization and Quality Control Peer Review Organization" because it is being added to the definitions in § 400.200 by another final rule published elsewhere in this issue of the Federal Register regarding the acquisition, protection and disclosure of PRO information.

We also are deleting the definitions of "area" and "PRO" in § 460.1. We are also deleting the definition of "PRO" in § 462.2 (that we are redesignating as § 462.1). These definitions are being deleted because they appear in 42 CFR Part 400 that is the general definition section for 42 CFR Chapter IV.

We are revising the definition of "payor organization" in the newly

redesignated § 462.1 to conform with section 1153(b)(2)(A) as amended by DRA.

M. Other Technical and Conforming Changes

We are revising Part 405, Subpart G that contains the reconsideration and appeals procedures for Medicare Part A services. Specifically, we are revising § 405.704 that lists actions that are initial determinations to cross-reference Parts 466 and 473 regarding initial and reconsidered determinations made by a PSRO or PRO.

We are revising § 412.44 (previously § 405.472(c)) regarding medical review requirements for hospitals under the prospective payment system to more accurately reflect a PRO's review responsibilities. As revised, this section is consistent with the description of PROs' responsibilities in § 466.70(c)(4), (5), (6), and (7).

We are revising § 412.82(b) (previously § 405.475(c)(2)) to provide that a medical review entity (for example, a PRO) grants grace days for day outliers under the prospective payment system for inpatient hospital care.

We are deleting references to PSROs in § 431.630 regarding the coordination of Medicaid with peer review organizations to conform to section 1902(d) of the Act.

In § 456.2 concerning States contracting with PSROs, we are deleting a cross-reference to § 431.630 since we are no longer referring to PSROs in that section in accordance with section 1902(D) of the Act.

Again, in accordance with section 1902(d) of the Act, we are deleting the cross-reference to § 431.630 in § 456.650. We also are revising the language in the proposed § 456.650(c)(3) for consistency with paragraph (c)(2). We are deleting the proposed § 456.652(d) that would have implemented a penalty provision for States, contracting with PSROs or PROs, if the State failed to submit a quarterly showing that it met physician certification, recertification and plan of care requirements. The DRA amendments which deleted sections 1903(g)(1)(A) and (B) of the Act, removed the penalty provision for those States not meeting these patient care requirements. Instead, the patient care requirements are now included under the State plan requirements located at section 1902(a)(44) of the Act.

We will not require that States, after they have entered into a contract with a PSRO or PRO, to submit quarterly showings that they meet the patient care requirements except for the first quarter following the effective date of the

contract. This will serve as notification to us to exclude that State or those particular facilities from our validation reviews. As specified in the proposed § 456.654(a)(5) and now in § 456.654(a)(4), if a facility is being reviewed by a PRO, the State need only list the date the PRO assumed review authority on the quarterly showing for that facility. However, a quarterly showing will continue to be required for any facility not being reviewed by a PRO or for any level of care that is still being reviewed by the State.

We are amending 42 CFR Part 462 regarding peer review organizations to establish a new Subpart A to include the definitions located at § 462.2. We are redesignating this section as § 462.1. Also in Part 462, we are making changes to §§ 462.102, 462.103 and 462.105 for clarity. We are revising § 462.105 to conform to section 1153(b)(3)(B) of the Act that defines an entity affiliated with a health care facility or association of facilities. We are further revising §§ 462.105 and 462.106 to conform to section 1153(b)(2)(A) that permits Medicare fiscal intermediaries to serve as PROs effective November 15, 1984. We are deleting the text at § 462.107(d)(2) because it duplicates the provisions contained in § 462.106.

V. Impact Analyses

A. Introduction

Executive Order 12291 requires us to prepare and publish a regulatory impact analysis for any regulations that are likely to have an annual effect on the economy of \$100 million or more, cause a major increase in costs or prices, or have a significant adverse effect on competition, employment, investment, productivity, or innovation. In addition, the Regulatory Flexibility Act, Pub. L. 96-354, requires us to prepare and publish a regulatory flexibility analysis for regulations unless the Secretary certifies that the regulations will not have a significant economic impact on a substantial number of small entities. Under both the Executive Order and the Regulatory Flexibility Act, such analyses must, when prepared, show that the agency issuing the regulations has examined alternatives that might minimize an unnecessary burden or otherwise ensure that the regulations are cost-effective.

In the Impact Analysis section of the proposed rule published on July 17, 1984, we stated that the effects of the regulation were not significant to the point of requiring a regulatory impact analysis or a regulatory flexibility analysis. However, after further review

of our proposed policies and as a result of substantive issues raised by the public commenters, we have decided to include a voluntary regulatory impact and regulatory flexibility analysis in this final rule. This analysis focuses primarily on the nature of the incremental differences between the PRO and PSRO programs and also on the impact of these differences on certain affected parties (e.g., the Federal government, hospitals, physicians, beneficiaries and recipients). Together with several specific comments noted in the preamble, the following discussion constitutes a voluntary analysis of this final rule.

B. Background

Since the inception of the Medicare program in 1965, and the Medicaid program in 1967, Utilization review has been an ongoing activity to assure that Federally reimbursed health care was furnished only when medically necessary. The Social Security Amendments of 1972 established the PSRO program to assure that the health services and items for which Federal payment is made conformed to appropriate professional standards and were delivered in the most efficient and economical manner possible. The Peer Review Improvement Act of 1982 focused on "... promoting effective, efficient, economical delivery of health care services and promoting the quality of services of the type for which payment may be made under this title ..." (Congressional Record—August 17, 1982, page H6185). Thus, throughout the history of the Medicare and Medicaid programs, utilization and peer review strategies have been maintained to safeguard program expenditures and the quality of services and items provided to programs beneficiaries.

C. PROs and PSROs—Differences and Similarities

As noted in the background discussion in the NPRM, there are differences and similarities between the PSRO and PRO programs. A general discussion of these points will focus on significant distinctions between these programs and the effect these differences have on affected parties.

There are notable differences between the two programs. They include:

- PROs are expected to achieve specific, outcome oriented measurable objectives. PSROs emphasized the process of review.
- The funding mechanism (PRO contracts vs. PSRO grants) and length of the agreement (2-year PRO contracts vs. 1-year PSRO grants).

- The responsibilities of PROs to monitor potential utilization and quality problems inherent in the prospective payment system (increased admissions, multiple transfers, early discharges, procedure coding abuse). PSRO review was not strongly focused on outcomes or system impact.

The similarities between the PRO and PSRO programs include:

- Safeguarding Medicare and Medicaid funds from unnecessary and inappropriate expenditures.
- Using various initiatives to educate physician and hospital staff regarding more effective, efficient and economical ways to provide health care services to program beneficiaries.
- Conducting medical reviews by peers.

In this analysis, we are focusing on the impact of the provisions in the rule that are new or modifications to the current peer review effort. In particular, we will examine the effects of the PROs' assumption of review on hospitals under the prospective payment system and for all other facilities, practitioners, and beneficiaries.

D. The Nature of Estimated Impacts Resulting from this Final Rule

In discussing the expected impacts (benefits, costs and behavioral changes) resulting from the final rule, several constraints limit our ability to determine the nature and extent of the impacts. First, PRO efforts are related to the purpose and goals of the prospective payment system. The prospective payment system endeavors to change hospital behavior through financial incentives under Medicare. The PROs act as a safeguard to assure that, as certain behavioral changes occur in response to prospective payment system incentives, program abuses do not occur to adversely affect beneficiaries or the Medicare program. Therefore, it will be difficult to differentiate clearly the impact of PRO efforts from those of the prospective payment system.

A second consideration is that States, other third-party payors and numerous business health care coalitions are also examining the behavior of hospitals and practitioners in hopes of reducing unnecessary and inappropriate expenditures and services. Their efforts, which in some case are the result of PROs' initiatives through private contractual arrangements, will also serve to reduce unnecessary and inappropriate admissions and services. While we view these efforts as beneficial in nature, they must be considered in determining the nature and extent of the effect of this final rule.

Finally, we believe that much of the impact of the PRO program results from the intent of Congress, as expressed in the statute, rather than from this final rule.

For these reasons we believe that the impact of these regulations, as distinct from the total impact of the PRO program, will not be singularly significant. However, apart from these considerations, it is certain that a substantial number of hospitals, practitioners, beneficiaries, recipients and other parties, including the Federal government, will be directly or indirectly affected by this final rule.

E. Impacts on Affected Parties

1. Medicare and Medicaid Programs.

As discussed in the Background section of this analysis, utilization and peer review programs have long been an integral part of both the Medicare and Medicaid programs. These medical review efforts have been safeguards over Federal expenditures for health care services and items furnished to Medicare and Medicaid beneficiaries. We believe that the PRO program will continue to assure that Federal funds will be spent only for necessary, reasonable and appropriate services and items and that beneficiaries will receive quality care.

To realize the continued safeguarding of Federal program expenditures and the provision of quality care, \$339 million will be spent on the two-year PRO contracts for the period from the fourth quarter FY 1984 through the third quarter of FY 1986. Investing these Federal funds will enable the PROs to meet their individual contract objectives (admission, quality of care and utilization goals), and will result in certain dollar benefits to the government in excess of total contract costs. Also, we believe that by reducing inappropriate utilization, more Federal funds would be freed to provide needed care for a greater number of beneficiaries and recipients. Furthermore, reducing unnecessary utilization will lessen possible health complications and deaths that at times result from unnecessary admissions and inappropriate procedures. Thus, we believe that the Federal government will realize benefits of greater value than its expenditures in its effort to safeguard Federal Medicare and Medicaid program expenditures.

2. Beneficiaries and Recipients.

Two issues of concern for Medicare beneficiaries and Medicaid recipients are the cost of health care, particularly out-of-pocket expenses, and the quality of care received from providers.

suppliers, and practitioners. As a result of PROs achieving their contractual objectives, we believe that beneficiaries and recipients will continue to receive necessary, reasonable and appropriate services and items. Beneficiaries, in particular, will be protected by PRO review from potential abuses that may result from the actions some providers may take in response to the incentives established by the prospective payment system (unnecessary increased admissions, inappropriate readmissions and unnecessary transfers to providers and units excluded from the prospective payment system.) Recipients in States operating under a cost reimbursement methodology will also benefit from the review activities of the PROs that will prevent unnecessary admissions and shortening lengths of stay. In both cases, individuals should save the out-of-pocket expenses (deductibles and coinsurance payment) related to unnecessary admissions, readmissions, transfers and lengths of stay.

In some instances, the impact of PRO review will be to change the site of service from inpatient to outpatient care. In these cases, the beneficiary would avoid paying the inpatient deductible amount (\$400 in 1985), but would pay the amount of the outpatient deductible and coinsurance. To the extent that the sum of the out-of-pocket expense for the Part B services is less than the Part A deductible, the beneficiary will incur less personal liability than if the service was performed in an inpatient setting.

Regarding the quality of care issue, we believe that beneficiaries and recipients will benefit from the peer review efforts of the PROs. In particular, we note that individual beneficiaries and recipients will be advantaged by the reduction in the number of inappropriate or unnecessary admissions or procedures; by the anticipated outcomes of certain required review activities; and by the achievement of overall PRO objectives aimed at significant improvement in patient quality care. For example, we expect PROs will reduce avoidable deaths and complications after surgery. To the extent that PROs can achieve these quality goals, beneficiaries will benefit from the PROs' efforts.

Therefore, in summary, beneficiaries and recipients can anticipate beneficial outcomes in several respects, especially reduced personal expenditures, avoidance of unnecessary or inappropriate health services, and avoidance of unnecessary death and complications. We qualify this conclusion by noting that some beneficiaries could incur additional

personal expenses under Part B if the site of care is changed from inpatient to an outpatient setting.

3. Health Care Facilities. Many of the public comments received on the proposed rule were from hospitals raising issues related to the impact of this rule on their operations. We are responding to many of these issues in the comment and response portion of the preamble. We also address in the preamble issues raised about other responsibilities and functions of health care facilities.

Earlier in this analysis, we discussed the difficulties encountered in estimating precisely the impact of this rule. We noted that the requirements of the PRO statute itself have an impact on facilities; that in many respects the incremental differences between the impact of the PSRO program and the PRO program are not significant; and that the influence of the prospective payment system and the efforts of other third-party payors will also affect facilities.

However, even given these qualifications, we can identify several areas of potential impact that may result from implementing the PRO program. In summary, they include:

- A potential increase in reporting, recordkeeping and photocopying burdens that were not specifically part of the prospective payment rate calculations. As explained earlier in the preamble, collection of this information is necessary for PROs to make determinations that the items and services provided by a facility are necessary and appropriate.

- A reduction in expected Medicare payments to health care facilities. Some facilities, especially hospitals, can minimize the impact of potential payment denials, by ensuring that admissions are medically necessary and appropriate.

- Changes in behavior regarding the numbers and types of admissions. We believe that these changes will result from reductions in unnecessary and inappropriate admissions and procedures. Many other behavioral changes will result from the financial incentives of the prospective payment system that will be reinforced by PRO activity.

We believe that many of these costs and additional burdens will be offset by identifiable benefits to the facilities. For example, by providing PROs with needed medical record information for the PROs' conduct of preadmission review, in many cases hospitals will avoid the more burdensome retrospective denial process.

In summation, we believe that all health care facilities will benefit from PRO activity, particularly in light of the increasing fiscal constraints that are affecting many facilities. We believe that PRO initiatives will be effective in reducing some operating expenses that would otherwise be spent on unnecessary or inappropriate services.

4. Physicians. In recent years, variations in physicians' hospital admission and procedure rates have come under particular examination for their influence on the cost and quality of health care. Recent studies identify several primary causes for these variations and conclude that they may occur because of "practice style" (Wennberg, *HEALTH AFFAIRS*, Summer 1984), "reliance on the opinions of peers" (Eddy, *HEALTH AFFAIRS*, Summer 1984), or "provider efficiency" (McClure, *HEALTH AFFAIRS*, Summer 1984).

The conclusion reached from these and other investigations is that variations in physician behavior may unnecessarily drive up health care costs and cause needless complications and even deaths. Historically, PSROs provided a peer review mechanism to examine the impact of physician decisions related to items in the general course of treatment, the appropriateness of the setting, and the length of an inpatient's stay. In many respects, PRO activities will also focus on similar concerns.

We received a number of public comments concerning the impact of PRO initiatives on physicians. In our responses, we consider some of the potential impacts resulting from provisions like the examination of practitioner records and the necessity for the cooperation of practitioners in the conduct of PRO reviews. However, it is difficult to isolate the impact of PRO activities alone on affected physicians. One reason is that the prospective payment system itself is causing significant direct and indirect changes in physician practice styles and behaviors (for example, in terms of admissions and decisions about elective surgery). Also, other third-party payor activities seek to influence physicians' practice styles. The combined effect of these initiatives is to provide physicians with economic incentives to alter their practice styles in order to reduce unnecessary expenditures while preserving the quality of health care.

However, we can cite several examples of potential impacts on affected physicians resulting from the PRO program. First, the change from local peer review (PSRO) to statewide

peer review (PRO) by expanding the geographic scope of reviewers, may contribute to a decrease in local practice variations within a State. Second, physicians may realize some reduction in Medicare revenues as the result of a PRO's decision concerning the necessity of an admission or the efficacy of a procedure. However, we believe that in most cases, overall reductions in physician income will not be significant because the majority will practice in accordance with accepted norms thereby avoiding the risk of payment denials.

In summary, we believe that PRO activities will affect many physicians. However, through the educational efforts of individual PROs, we believe that unnecessary admissions and procedures will be reduced. This in turn would lead to reduction in the number of denials for submitted claims and the accompanying administrative burdens associated with processing denied claims.

F. Conclusion

In the introduction to this analysis, we stated that we are performing a voluntary regulatory impact and flexibility analysis. This decision results from a further examination of the effects of our proposed policies and because of the number of public comments received on several substantive issues. We conclude that a substantial number of health care facilities, beneficiaries, recipients and physicians are affected by the PRO program. However, we believe that the impact directly attributable to these final regulations is not significant for three reasons:

- The primary impact results from the requirements of the PRO statute itself.
- The incremental differences between most PRO and previous peer review activities are not significant.
- The effect of PRO activities may not be the primary cause of these impacts. Other factors, such as the prospective payment system and other third-party payor review efforts, may have a greater impact than the PRO activities.

For the reasons noted above, we have determined that this final rule does not meet the threshold criteria set forth in Executive Order 12291. Furthermore, we have determined, and the Secretary certifies, that this final rule will not have a significant effect on a substantial number of small entities under the Regulatory Flexibility Act of 1980.

VI. Information Collection Requirements

Sections 412.44 (previously 405.472), 431.630, 456.654, 466.70, 466.72, 466.74, 466.78, 466.80 and 466.94 of this rule

contain information collection requirements. They are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507). The public is not required to comply with the information collection requirements until OMB approves these requirements under section 3507 of the Paperwork Reduction Act of 1980. Comments on this requirement should be sent directly to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, Washington, D.C., Attention: Faye Ludicello. A notice will be published in the *Federal Register* when approval is obtained.

VII. Waiver of Proposed Rulemaking

The Administrative Procedure Act (5 U.S.C. 553) requires us to publish a general notice of proposed rulemaking in the *Federal Register*, and afford prior public comment on proposed rules. Such notice includes a statement of the time, place, and nature of rulemaking proceedings, reference to the legal authority under which the rule is proposed, and the terms or substance of the proposed rule or a description of the subjects and issues involved. However, this requirement does not apply when an agency finds good cause that such a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and its reasons in the rules issued.

These final rules include revisions to conform the regulations to sections 2315(d), 2334 and 2347 of the Deficit Reduction Act of 1984. Because these conforming changes do not involve significant discretion or the addition of significant procedure or detail for implementation, we believe that there is good cause to waive a proposed rulemaking as unnecessary. Furthermore, the changes made to conform the regulations to the DRA amendments are less stringent than existing regulations. Therefore, it is also in the public interest to waive the proposed rulemaking.

VIII. List of Subjects

42 CFR Part 400

Definitions, OMB control numbers.

42 CFR Part 405

Administrative practice and procedure, Certification of compliance, Clinics, Contracts (Agreements), End-Stage Renal Disease (ESRD), Health care, Health facilities, Health maintenance organizations (HMO), Health professions, Health suppliers,

Home health agencies, Hospitals, Inpatients, Kidney diseases, Laboratories, Medicare, Nursing homes, Onsite surveys, Outpatient providers, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 431

Administrative practice and procedure, Contracts (Agreements), Fair hearings, Federal financial participation, Grant-in-Aid program—health, Health facilities, Health maintenance organizations (HMO), Indians, Information (Disclosure), Medicaid, Mental health centers, Prepaid health plans, Privacy, Quality control, Reporting and recordkeeping requirements.

42 CFR Part 433

Administrative practice and procedure, Assignment of Rights, Claims, Contracts (Agreements), Cost allocation, Federal financial participation, Federal matching provision, Grant-in-Aid program—health, Mechanized Claims Processing and Information Retrieval Systems, Medicaid, State fiscal administration, Third party liability.

42 CFR Part 456

Administrative practice and procedure, Grant-in-Aid program—health, Health facilities, Medicaid, Mental health centers, Nursing homes, Penalties, Reporting and recordkeeping requirements, Utilization control, Utilization review.

42 CFR Part 460

Health care, Health professions, Hospitals, Physicians, Professional Standards Review Organizations (PSRO).

42 CFR Part 462

Grant-in-Aid program—health, Health care, Professional Standards Review Organizations (PSRO).

42 CFR Part 466

Appeals, Delegation, Denials, Grant-in-Aid program—health, Health care, Health facilities, Health professions, Hospitals, Hospital review, Norms/criteria/standards, Physicians, Professional Standards Review Organizations (PSRO), Reconsiderations, Utilization and Quality Control Peer Review Organizations (PRO).

42 CFR Chapter IV is amended as set forth below:

I. The table of contents is amended by revising the title of Part 466 as follows:

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER D—PEER REVIEW ORGANIZATIONS

Part 466—Utilization and Quality Control Review

PART 400—INTRODUCTIONS; DEFINITIONS

The authority citation for Part 400 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

II. Section 400.200 is amended by adding in alphabetical order, the definition of "Area" to read as follows:

§ 400.200 General definitions.

"Area" means the geographical area within the boundaries of a State or a State or other jurisdiction designated as constitution an area with respect to which a Professional Standards Review Organization or a Utilization and Quality Control Peer Review Organization has been or may be designated.

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

III. Part 405 is amended as follows:

A. The authority citation for Subpart C is revised to read as follows:

Authority: Secs. 1102, 1154(a)(2)(B), 1815, 1833, 1842, 1862, 1866, 1870, 1871, and 1879 of the Social Security Act (42 U.S.C. 1302, 1320c-3(a)(2)(B), 1395g, 1395l, 1395u, 1395y, 1395cc, 1395gg, 1395hh, 1395pp), and 31 U.S.C. 3711.

B. In Subpart C, § 405.330 is amended by revising paragraph (b) to read as follows:

§ 405.330 Payment for certain nonreimbursable expenses.

(b) Payment may be made under this provision for not more than 2 days for inpatient hospital services, post-hospital, SNF care, or home health services (as defined in §§ 409.10, 409.20, and 409.40, respectively) when the fiscal intermediary or PRO determines that additional time is required in order to arrange for post discharge care, and when the additional care is furnished after whichever of the following days is the earlier:

(1) The day on which the individual to whom the services were furnished, has been determined, under § 405.332(a), to have knowledge, actual or imputed, that those services were excluded from coverage by reason of § 405.310(g) or § 405.310(k); or

(2) The day on which the provider of the services, has been determined, under § 405.332(b), to have knowledge, actual or imputed, that the services were excluded from coverage as custodial care (§ 405.310(g)) or as not reasonable and necessary (§ 405.310(k)).

C. The authority citation for Subpart G continues to read as follows:

Authority: Secs. 1102, 1154, 1155, 1869(b), 1871, 1872 and 1879 of the Social Security Act (42 U.S.C. 1302, 1320c, 1395ff(b), 1395hh, 1395ii and 1395pp).

In § 405.704(b), the introductory paragraph is reprinted, and paragraphs (b)(11) and (b)(12) are revised to read as follows:

§ 405.704 Actions which are initial determinations.

(b) *Requests for payment by or on behalf of individuals.* An initial determination with respect to an individual includes any determination made on the basis of a request for payment by or on behalf of the individual under Part A of Medicare, including a determination with respect to:

(11) The medical necessity of services (See Parts 466 and 473 of this chapter for provisions pertaining to initial and reconsidered determinations made by a PSRO or PRO.);

(12) When services are excluded from coverage as custodial care (§ 405.310(g)) or as not reasonable and necessary (§ 405.310(k)), whether the individual or the provider of services who furnished the services, or both, knew or could reasonably have been expected to know that the services were excluded from coverage (see § 405.332); and

PART 412—PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT HOSPITAL SERVICES

The authority citation for Part 412 continues to read as follows:

Authority: Secs. 1102, 1871 and 1886 of the Social Security Act (42 U.S.C. 1302, 1395hh, 1395ww).

IV. Part 412 is amended as follows:

A. In § 412.44, the introductory language is reprinted without change for the convenience of the reader, paragraph (a) is revised and

redesignated as paragraph (b), a new paragraph (a) is added, paragraphs (b) and (c) are redesignated as (c) and (d), and a new paragraph (e) is added. As revised § 412.44 reads as follows:

§ 412.44 Medical review requirements: Admissions and quality review.

Beginning on November 15, 1984, a hospital must have an agreement with a Utilization and Quality Control Peer Review Organization (PRO) to have the PRO review, on an ongoing basis, the following:

(a) The medical necessity, reasonableness and appropriateness of hospital admissions and discharges.

(b) The medical necessity, reasonableness and appropriateness of inpatient hospital care for which additional payment is sought under the outlier provisions of §§ 412.82 and 412.84 of this chapter.

(c) The validity of the hospital's diagnostic and procedural information.

(d) The completeness, adequacy, and quality of the services furnished in the hospital.

(e) Other medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries.

B. Section 412.82 is amended by revising paragraph (b) to read as follows:

§ 412.82 Payment for extended length of stay cases (day outliers).

(b) The medical review entity (that is, a PSRO, PRO, or intermediary) must review and approve to the extent required by HCFA—

(1) The medical necessity and appropriateness of the admission and outlier services in the context of the entire stay;

(2) The validity of the diagnostic and procedural coding; and

(3) The granting of grace days.

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

The authority citation for Part 431 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act, (42 U.S.C. 1302), unless otherwise noted.

V. Part 431 is amended as follows:

A. The table of contents for Part 431 is amended by revising the title of § 431.630 to read as follows:

Subpart M—Relations With Other Agencies

431.630 Coordination of Medicaid with PROs.

B. In § 431.630, the editorial note is removed and the section is revised to read as follows:

§ 431.630 Coordination of Medicaid with PROs.

(a) The State plan may provide for the review of Medicaid services through a contract with a PRO designated under Part 462 of this chapter. Medicaid requirements for medical and utilization review are deemed to be met for those services or providers subject to review under the contract.

(b) The State plan must provide that the contract with the PRO—

(1) Meets the requirements of § 434.6(a) of this part;

(2) Includes a monitoring and evaluation plan by which the State ensures satisfactory performance by the PRO;

(3) Identifies the services and providers subject to PRO review;

(4) Ensures that the review activities performed by the PRO are not inconsistent with PRO review activities of Medicare services and includes a description of whether and to what extent PRO determinations will be considered conclusive for Medicaid payment purposes.

PART 433—STATE FISCAL ADMINISTRATION

VI. Part 433 is amended as follows:

A. The authority citation for Part 433 is revised to read as follows:

Authority: Secs. 1102, 1902(a)(25), 1903(a)(3), 1903(d)(2), 1903(d)(5), 1903(o), 1903(p), and 1912 of the Social Security Act (42 U.S.C. 1302, 1396a(a)(25), 1396b(a)(3), 1396b(d)(2), 1396b(d)(5), 1396b(o), 1396b(p), and 1396(k), unless otherwise noted.

B. Section 433.15 is amended by revising paragraph (b)(6)(i) to read as follows:

§ 433.15 Rates of FFP for administration.

(b) *Activities and rates.*

(6)(i) Funds expended for the performance of medical and utilization review by a PRO under a contract entered into under section 1902(d) of the Act; 75 percent (section 1903(a)(3)(C) of the Act).

PART 456—UTILIZATION CONTROL

The authority citation for Part 456 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act, 49 Stat. 647 (42 U.S.C. 1302).

VII. Part 456 is amended as follows:

A. Section 456.2 is amended by revising paragraph (b) to read as follows:

§ 456.2 State plan requirements.

(b) These requirements may be met by the agency by:

(1) Assuming direct responsibility for assuring that the requirements of this Part are met;

(2) Deeming, if the agency contracts with a PSRO designated under Part 462 of this chapter; or

(3) Deeming of medical and utilization review requirements if the agency contracts with a PRO to perform that review, which in the case of inpatient acute care review will also serve as the initial determination for PRO medical necessity and appropriateness review for patients who are dually entitled to benefits under Medicare and Medicaid.

B. Section 456.650(c) is revised to read as follows:

§ 456.650 Basis, purpose and scope.

(c) *Scope.* The reductions required by this subpart do not apply to—

(1) Services provided under a contract with a health maintenance organization;

(2) Facilities in which a PSRO is performing review under contract with the Medicaid agency, but only until a contract is awarded in the area to a PRO; or

(3) Facilities in which a PRO is performing medical and utilization reviews under contract with the Medicaid agency in accordance with § 431.630 of this chapter.

C. In § 456.654(a), the introductory language is reprinted; paragraph (a)(4) is revised to include requirements for PRO reviews; paragraph (a)(6) is amended to change "as" to "an" and "provided" to "provider"; and paragraph (a)(7) is amended to change "facility and" to "facility that". The revised § 456.654(a)(4) reads as follows:

§ 456.654 Requirements for content of showings and procedures for submittal.

(a) An agency's showing for a quarter must—

(4) If review has been contracted to a PRO under § 431.630 of this chapter or to a PSRO, list the date the PRO or PSRO contracted for review.

PART 460—AREA DESIGNATIONS

The authority citation for Part 460 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act, 42 U.S.C. 1302. Subpart A is also issued under sec. 150 of Pub. L. 97-248, 42 U.S.C. 1320c note. Subpart B is also issued under secs. 1151 and 1153 of the Social Security Act, 42 U.S.C. 1320c and 1320c-2.

§ 460.1 [Amended]

VIII. Section 460.1 is amended by removing the definitions of "Area" and "PRO".

IX. Part 462 is amended as follows:

A. The table of contents is revised to reflect the establishment of a new Subpart A—General Provisions, to include the current § 462.2 which is redesignated as § 462.1; the redesignation of the current Subpart A as Subpart B to include the current § 462.1 which is redesignated as § 462.2 and the current §§ 462.3–462.16; the redesignation of the current Subpart B as Subpart C to include the current §§ 462.100–462.107; and the revision of the authority citation to read as follows:

PART 462—PEER REVIEW ORGANIZATIONS

Subpart A—General Provisions

Sec.

462.1 Definitions.

Subpart B—PSRO

462.2 Scope and applicability.

462.3 Eligibility for grants.

462.4 Requirements for designation as a priority PSRO.

462.5 Requirements for designation as an alternate PSRO.

462.6 Application requirements for conditional designation.

462.7 [Reserved]

462.8 Conditional designation as a PSRO.

462.9 [Reserved]

462.10 Limitation on period of conditional designation.

462.11 Duration, renewal and voluntary termination or nonrenewal of grants.

462.12 Involuntary termination of non-renewal or grants.

462.13 Use of grant funds.

462.14 Publications and copyrights.

462.15 Applicability of 45 CFR Part 74.

462.16 Additional terms and conditions.

Subpart C—Utilization and Quality Control Peer Review Organizations

462.100 Scope and applicability.

462.101 Eligibility requirements for PRO contracts.

462.102 Eligibility of physician-sponsored organizations.

462.103 Eligibility of physician-access organizations.

462.104 Requirements for demonstrating ability to perform review.

462.105 Prohibition against contracting with health care facilities.

462.106 Prohibition against contracting with payor organizations.

462.107 PRO contract award.

Authority: Sec. 1102 of the Social Security Act, 42 U.S.C. 1302. Subpart B is also issued under sec. 150 of Pub. L. 97-248 U.S.C. 1320c note, Subpart C is also issued under secs. 1152 and 1153 of the Social Security Act, U.S.C. 1320c and 1320-2.

B. The current Subparts A and B are redesignated as Subparts B and C, respectively.

C. 1. A new Subpart A—General Provisions is established to include the current § 462.2 which is redesignated as § 462.1.

2. The newly designated § 462.1 is amended by removing the definition of "PRO" and by revising the definition of "Payor organization" to read as follows:

§ 462.1 Definitions.

"Payor organization" means any organization, other than a self-insured employer, which makes payments directly or indirectly to health care practitioners or providers whose health care services are reviewed by the organization or would be reviewed by the organization if it entered into a PRO contract. "Payor organization" also means any organization which is affiliated with any entity which makes payments as described above, by virtue of the organization having two or more governing body members who are also either governing body members, officers, partners, 5 percent or more owners or managing employees in a health maintenance organization or competitive medical plan.

§ 462.1 [Redesignated as § 462.2]

D. The newly designated Subpart B is amended by redesignating the current § 462.1 as § 462.2.

E. The newly designated Subpart C is amended as follows:

1. Section 462.102 is amended by revising paragraph (a) to read as follows:

§ 462.102 Eligibility of physician-sponsored organizations.

(a) In order to be eligible for designation as a physician-sponsored PRO, an organization must meet the following conditions:

(1) Be composed of a substantial number of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area and who are representative of the physicians practicing in the area.

(2) Not be a health care facility, health care facility association, or health care facility affiliate, as specified in § 462.105.

2. Sections 462.103, 462.105, and 462.106 are revised to read as follows:

§ 462.103 Eligibility of physician-access organizations.

(a) In order to be eligible for designation as a physician-access PRO, an organization must meet the following conditions:

(1) Have available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy practicing medicine or surgery in the review area to assure adequate peer review of the services provided by the various medical specialties and subspecialties.

(2) Not be a health care facility, health care facility association, or health care facility affiliate, as specified in § 462.105.

(b) An organization meets the requirements of paragraph (a)(1) of this section if it demonstrates—

(1) That it has available to it at least one physician in every generally recognized specialty; and

(2) The existence of an arrangement or arrangements with physicians under which the physicians would conduct review for the organization.

§ 462.105 Prohibition against contracting with health care facilities.

(a) *Basic rule.* Except as permitted under paragraph (b) of this section, the following are not eligible for PRO contracts:

(1) A health care facility in the PRO area.

(2) An association of health care facilities in the PRO area.

(3) A health care facility affiliate; that is, an organization in which more than 20 percent of the members of the governing body are also either a governing body member, officer, partner, five percent or more owner, or managing employee in a health care facility or association of health care facilities in the PRO area.

(b) *Exceptions.* Effective November 15, 1984, the prohibition stated in paragraph (a) of this section will not apply to a payor organization if HCFA determines under § 462.106 that there is no other eligible organization available.

(c) *Subcontracting.* A PRO must not subcontract with a facility to conduct any review activities except for the review of the quality of care.

§ 462.106 Prohibition against contracting with payor organizations.

Payor organizations are not eligible to become PROs for the area in which they make payments until November 15, 1984.

If no PRO contract for an area is awarded before November 15, 1984, a payor organization will be determined eligible by HCFA, if an eligible organization that is not a payor organization is unavailable at that time. HCFA may determine the unavailability of nonpayor organizations based on the lack of response to an appropriate Request for Proposal.

3. In § 462.107, the introductory language is reprinted, and paragraph (d) is revised to read as follows:

§ 462.107 PRO contract award.

HCFA, in awarding PRO contracts, will take the following actions—

(d) Subject to the limitations established by §§ 462.105 and 462.106, award the contract for the given PRO area to the selected organization for a period of two years.

X. Part 466 is amended as set forth below:

A. The title of Part 466 is revised to read as set forth below.

B. The table of contents is amended to reflect the revision of Subpart A—"General Provisions" to include only current § 466.2, which is redesignated as § 466.1, the revision of the title and contents of Subpart B—PSRO Review, to include current § 466.1 which is redesignated as § 466.2 and current §§ 466.3 through 466.63 with center headings, the removal of the headings of Subparts D and E and the revision of the heading of Subpart C. As revised, the table of contents reads as follows:

PART 466—UTILIZATION AND QUALITY CONTROL REVIEW

Subpart A—General Provisions

Sec.
466.1 Definitions.

Subpart B—PSRO Review

General

- 466.2 Statutory provisions and applicability.
- 466.3 Review objectives.
- 466.4 Examination of the operation and records of hospitals.
- 466.5 Refusal of hospital to allow PSRO entry and performance of review.
- 466.6 Reports to HCFA.
- 466.10 General requirements for concurrent review.
- 466.11 Admission review.
- 466.12 Continued stay review.
- 466.13 Elective procedures review.
- 466.14 Preadmission review.
- 466.15 Modifications of review activities.
- 466.16 Notice of adverse determination.
- 466.17 Informing discharge planners.
- 466.18 Medical care evaluation (MCE) studies.
- 466.19 Profile analysis.

- 466.20 Involvement of health care practitioners other than physicians.
466.21 Reviewer qualifications and participation.
466.22 Alternative review methods.

Delegated Review

- 466.30 Opportunity for hospitals to seek delegation.
466.31 Letter of interest.
466.32 Details of delegated review plan.
466.33 Determination and notice of hospital capability.
466.34 Delegation of review activities.
466.35 Agreement with delegated hospitals.
466.36 PSRO monitoring and reassessment of hospital capability.
466.37 Reconsiderations.
466.38 Monitoring by HCFA.
466.39 PSRO responsibilities when delegation is denied, withdrawn, or disapproved.

Norms, Criteria, and Standards for Review

- 466.50 Basic requirement for PSRO area norms, criteria, and standards.
466.51 Establishment of norms, criteria, and standards.
466.52 Dissemination of norms, criteria, and standards.
466.53 Use of norms, criteria, and standards.
466.54 Revisions.
466.55 Regional norms, criteria, and standards.
466.56 Review of PSRO norms, criteria, and standards.

Financing of Review Activities

- 466.60 Applicability and scope.
466.61 Areawide budget.
466.62 Reimbursement to delegated hospitals.
466.63 Reimbursement for nondelegated hospitals.

Subpart C—Review Responsibilities of Utilization and Quality Control Peer Review Organizations (PROs)

General Provisions

- 466.70 Statutory bases, applicability and provisions.
466.72 Notification of PRO designation and implementation of review.
466.74 General requirements for assumption of review.
466.76 Cooperation with health care facilities.
466.78 Responsibilities of health care facilities.
466.80 Coordination with Medicare fiscal intermediaries and carriers.
466.82 Continuation of functions not assumed by PROs.

PRO Review Functions

- 466.83 Initial denial determinations.
466.84 Changes as a result of DRG validations.
466.85 Conclusive effect of PRO initial denial determinations and changes as a result of DRG validations.
466.86 Correlation of Title XI functions with Title XVIII functions.
466.88 Examination of the operations and records of health care facilities.

- 466.90 Lack of cooperation by a health care facility or practitioner.
466.92 General requirements for PRO review.
466.93 Opportunity to discuss proposed initial denial determination and changes as a result of a DRG validation.
466.94 Notice of PRO initial denial determination and changes as a result of a DRG validation.
466.96 Review period and reopening of initial denial determinations and changes as a result of DRG validations.
466.98 Reviewer qualifications and participation.
466.100 Use of norms and criteria.
466.102 Involvement of health care practitioners other than physicians.
466.104 Coordination of activities.

Authority: Sec. 1102 of the Social Security Act, 42 U.S.C. 1302. Subpart B is also issued under sec. 150 of Pub. L. 97-248, 42 U.S.C. 1320c note. Subpart C is also issued under secs. 1151-1163, and 1868(a) of the Social Security Act, 42 U.S.C. 1320c-1320-12, and 1395cc(a).

C. Section 466.1 is redesignated as § 466.3 and § 466.2 is redesignated as § 466.1.

D. Newly designated § 466.1 is amended by removing definitions of "Act", "HCFA", "Health care service", "National Council", "Other Attending Health Care Practitioner" and "Secretary" and revising the definitions of "Active staff privileges", "Admission review", "Concurrent quality assurance", "Concurrent review", "Continued stay review", "Delegated Hospital", "Length-of-stay norms", "Length-of-stay projection", "Non-delegated hospital", "Norm", "Physician", "Quality Review Study", "Skilled nursing facility (SNF)", "Working day", and adding in alphabetical order, the definitions of "Diagnosis-Related Group (DRG)", "DRG Validation", "Five Percent or more owner", "Health care facility or facility", "Non-facility organization", "Outliers", "Practitioner", "Preadmission certification", "Preadmission review", "Preprocedure review", "PRO review", "Retrospective review", "Review responsibility", "State survey agency," and "Subcontractor" as follows:

§ 466.1 Definitions.

Active staff privileges means: (a) That a physician is authorized on a regular, rather than infrequent or courtesy, basis: (1) To order the admission of patients to a facility; (2) to perform diagnostic services in a facility; or (3) to care for and treat patients in a facility; or (b) that a health care practitioner other than a physician is authorized on a regular, rather than infrequent or courtesy, basis to order the admission of patients to a facility.

Admission review means a review and determination by a PSRO or a PRO of the medical necessity and appropriateness of a patient's admission to a specific facility.

Concurrent quality assurance means a form of PSRO review that focuses on the quality of health services furnished to individual patients, and is performed while the patient is in the hospital.

Concurrent review means a review and determination that is focused on the necessity and appropriateness of inpatient hospital services and is performed while the patient is in the hospital. It includes admission review, continued stay review and, when appropriate, procedure review.

Continued stay review means PSRO or PRO review that is performed after admission review and during a patient's hospitalization to determine the medical necessity and appropriateness of continuing the patient's stay at a hospital level of care.

Delegated hospital means a hospital to which PSRO review functions are delegated under Subpart B.

Diagnosis related group (DRG) means a system for classifying inpatient hospital discharges. DRGs are used for purposes of determining payment to hospitals for inpatient hospital services under the Medicare prospective payment system.

DRG validation means a part of the prospective payment system in which a PRO validates that DRG assignments are based on the correct diagnostic and procedural information.

Five percent or more owner means a person (including, where appropriate, a corporation) who:

- Has an ownership interest of 5 percent or more;
- Has an indirect ownership interest equal to 5 percent or more;
- Has a combination of direct and indirect ownership interests (the possession of equity in the capital, the stock, or the profits of an entity) equal to five percent or more; or
- Is the owner of an interest of five percent or more in any obligation secured by an entity, if the interest equals at least five percent of the value of the property or assets of the entity.

Health care facility or facility means an organization involved in the delivery of health care services for which reimbursement may be made in whole or in part under Title XVIII of the Act.

Length-of-stay norms means established statistical measures of average lengths of stay for patients of similar age and diagnosis or condition.

Length-of-stay projection means a criterion that defines the time at which patients of similar age and diagnosis or condition would be expected to be ready for discharge.

Non-facility organization means a corporate entity that (1) is not a health care facility; (2) is not a 5 percent or more owner of a facility; and (3) is not owned by one or more health care facilities or association of facilities in the PRO area.

Nondelegated hospital means a hospital in which the PSRO conducts review activities using its own review procedures, and to which it has not delegated review activities under Part 466, Subpart B of this chapter.

Norm means a pattern of performance in the delivery of health care services that is typical for a specified group.

Outliers means those cases that have either an extremely long length of stay or extraordinarily high costs when compared to most discharges classified in the same DRG.

Physician means a doctor of medicine or osteopathy or another individual who is authorized under State or Federal law to practice medicine and surgery, or osteopathy. This includes medical officers in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

Practitioner means an individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients.

Preadmission certification means a favorable determination, transmitted to the hospital and the fiscal intermediary, approving the patient's admission for payment purposes.

Preadmission review means review prior to a patient's admission to a hospital to determine, for payment purposes, the reasonableness, medical necessity and appropriateness of placement at an acute level of care.

Preprocedure review means review of a surgical or other invasive procedure prior to the conduct of the procedure.

PRO review means review performed in fulfillment of a contract with HCFA, either by the PRO or its subcontractors.

Quality review study means an assessment conducted by or for a PRO of a patient care problem for the purpose of improving patient care

through peer analysis, intervention, resolution of the problem and follow-up.

Retrospective review means review that is conducted after services are provided to a patient. The review is focused on determining the appropriateness, necessity, quality, and reasonableness of health care services provided.

Review responsibility means (1) the responsibility of the PRO to perform review functions prescribed under Part B of Title XI of the Act and the Social Security Amendments of 1983 (Pub. L. No. 98-21) and the regulations of this part; (2) the responsibility to fulfill the terms and meet the objectives set forth in the negotiated contract between HCFA and the PRO; and (3) the authority of a PRO to make conclusive initial denial determinations regarding the medical necessity and appropriateness of health care and changes as a result of DRG validations.

Skilled nursing facility (SNF) means a health care institution or distinct part of an institution that (a) is primarily engaged in providing skilled nursing care or rehabilitative services to injured, disabled, or sick persons, and (b) has an agreement to participate in Medicare or Medicaid or both, and (c) is not a Christian Science sanatorium operated or listed and certified by the First Church of Christ Scientist, Boston, Massachusetts.

State survey agency means an agency performing provider surveys in accordance with an agreement under § 405.685 of this chapter.

"Subcontractor" means a facility or a non-facility organization under contract with a PRO to perform PRO review functions.

Working day means any one of at least five days of each week (excluding, at the option of each PSRO or PRO, legal holidays) on which the necessary personnel are available to perform review.

Subparts B through E—[Amended]

E. The headings for Subparts C, D, and E are removed, and §§ 466.30 through 466.63 are incorporated into Subpart B. Subpart B is amended by revising the title to read "PSRO Review", including the newly redesignated § 466.2 and incorporating therein current §§ 466.3 through 466.63, and adding center headings as follows: Center heading "Delegated Review" is added immediately before § 466.30, center heading "Norms, Criteria, and Standards for Review" is added immediately before § 466.50 and center

heading "Financing of Review Activities" is added immediately before § 466.60.

F. Subpart C consisting of §§ 466.70 through 466.104 is added to read as follows:

Subpart C—Review Responsibilities of Utilization and Quality Control Peer Review Organizations (PROs)

General Provisions

§ 466.70 Statutory bases, applicability and provisions.

(a) **Statutory basis.** Sections 1154, 1896(a)(1)(F) and 1886(f)(2) of the Act require that a PRO review those services furnished by physicians, other health care professionals, providers and suppliers as specified in its contract with the Secretary.

(b) **Applicability.** The regulations in this subpart apply to review conducted by a PRO and its subcontractors.

(c) **Scope of PRO review.** In its review, the PRO must determine (in accordance with the terms of its contract)—

(1) Whether the services are or were reasonable and medically necessary for the diagnosis and treatment of illness or injury or to improve functioning of a malformed body member, or (with respect to pneumococcal vaccine) for prevention of illness or (in the case of hospice care) for the palliation and management of terminal illness;

(2) Whether the quality of the services meets professionally recognized standards of health care;

(3) Whether those services furnished or proposed to be furnished on an inpatient basis could, consistent with the provisions of appropriate medical care, be effectively furnished more economically on an outpatient basis or in an inpatient health care facility of a different type;

(4) Through DRG validation, the validity of diagnostic and procedural information supplied by the hospital;

(5) The completeness, adequacy and quality of hospital care provided;

(6) The medical necessity, reasonableness and appropriateness of hospital admissions and discharges;

(7) The medical necessity, reasonableness and appropriateness of inpatient hospital care for which additional payment is sought under the outlier provisions of §§ 412.82 and 412.84 of this chapter; and

(8) Whether a hospital has misrepresented admission or discharge information or has taken an action that results in—

(i) The unnecessary admission of an individual entitled to benefits under Part A;

(ii) Unnecessary multiple admissions of an individual; or

(iii) Other inappropriate medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries.

(d) *Payment determinations.* On the basis of the review specified under paragraphs (c) (1), (3), (6) and (7), and (8) of this section, the PRO must determine whether payment may be made for these services. A PRO may grant a period of not more than two days (grace days) for the purpose of arranging post discharge care when the provider did not know or could not reasonably be expected to have known that payment for the service(s) would not be made under the Medicare program as specified in § 405.330(b).

(e) *Other duties and functions.* (1) The PRO must review at least a random sample of hospital discharges each quarter and submit new diagnostic and procedural information to the Medicare fiscal intermediary or carrier if it determines that the information submitted by the hospital was incorrect.

(2) The PRO must also perform other duties, functions, and responsibilities as required by HCFA.

§ 466.72 Notification of PRO designation and implementation of review.

(a) *Notice of HCFA's decision.* HCFA sends written notification of a PRO contract award to the State survey agency and Medicare fiscal intermediaries and carriers. The notification includes the effective dates of the PRO contract and specifies the area and types of health care facilities to be reviewed by the PRO. The PRO must make a similar notification when review responsibilities are subcontracted.

(b) *Notification to health care facilities and the public.* As specified in its contract with HCFA, the PRO must—

(1) Provide to each health care facility scheduled to come under review, a timely written notice that specifies the date and manner in which the PRO proposes to implement review, and the information to be furnished by the facility to each Medicare beneficiary upon admission as specified in § 466.78(b)(3) of this part.

(2) Publish, in at least one local newspaper of general circulation in the PRO area, a notice that states the date the PRO will assume review responsibilities and lists each area health care facility to be under review. The PRO must indicate that its plan for the review of health care services as approved in its contract with HCFA is available for public inspection in the PRO's business office and give the

address, telephone number and usual hours of business.

§ 466.74 General requirements for the assumption of review.

(a) A PRO must assume review responsibility in accordance with the schedule, functions and negotiated objectives specified in its contract with HCFA.

(b) A PRO must notify the appropriate Medicare fiscal intermediary or carrier of its assumption of review in specific health care facilities no later than five working days after the day that review is assumed in the facility.

(c) A PRO must maintain and make available for public inspection at its principal business office—

(1) A copy of each agreement with Medicare fiscal intermediaries and carrier;

(2) A copy of its currently approved review plan that includes the PRO's method for implementing review; and

(3) Copies of all subcontracts for the conduct of review.

(d) A PRO must not subcontract with a facility to conduct any review activities except for the review of the quality of care. The PRO may subcontract with a non-facility organization to conduct review in a facility.

(e) If required by HCFA, a PRO is responsible for compiling statistics based on the criteria contained in § 405.332 of this chapter and making limitation of liability determinations on excluded coverage of certain services that are made under section 1879 of the Act. If required by HCFA, PROs must also notify a provider of these determinations. These determinations and further appeals are governed by the reconsideration and appeals procedures in Part 405, Subpart G of this chapter for Medicare Part A related determinations and Part 405, Subpart H of this chapter for Medicare Part B related determinations.

(f) A PRO must make its responsibilities under its contract with HCFA, primary to all other interests and activities that the PRO undertakes.

§ 466.76 Cooperation with health care facilities.

Before implementation of review, a PRO must make a good faith effort to discuss the PRO's administrative and review procedures with each involved health care facility.

§ 466.78 Responsibilities of health care facilities.

(a) Beginning November 15, 1984, every hospital seeking payment for services provided to Medicare beneficiaries must maintain a written

agreement with a PRO operating in the area in which the hospital is located. These agreements must provide for the PRO review specified in § 466.70(c).

(b) *Cooperation with PROs.* Health care facilities that submit Medicare claims must cooperate in the assumption and conduct of PRO review. Facilities must—

(1) Allocate adequate space to the PRO for its conduct of review at the times the PRO is conducting review.

(2) Provide patient care data and other pertinent data to the PRO at the time the PRO is collecting review information that is required for the PRO to make its determinations. When review is performed away from the facility, the facility must photocopy and deliver to the PRO, without charge, all required information within 30 days of a request. When the PRO does post-admission, preprocedure review, the facility must provide the necessary information before the procedure is performed, unless it must be performed on an emergency basis.

(3) Inform Medicare beneficiaries at the time of admission, in writing, that the care for which Medicare payment is sought will be subject to PRO review and indicate the potential outcomes of that review. Furnishing this information to the patient does not constitute notice, under § 405.332(a) of this chapter, that can support a finding that the beneficiary knew the services were not covered.

(4) When the facility has issued a written determination in accordance with § 412.42(c)(3) of this chapter that a beneficiary no longer requires inpatient hospital care, it must submit a copy of its determination to the PRO within 3 working days.

(5) Assure, in accordance with the provisions of its agreement with the PRO, that each case subject to preadmission review has been reviewed and approved by the PRO before admission to the hospital or a timely request has been made for PRO review.

(6)(i) Agree to accept financial liability for any admission subject to preadmission review that was not reviewed by the PRO and is subsequently determined to be inappropriate or not medically necessary.

(ii) The provisions of paragraph (b)(6)(i) of this section do not apply if a facility, in accordance with its agreement with a PRO, makes a timely request for preadmission review and the PRO does not review the case timely. Cases of this type are subject to retrospective prepayment review under paragraph (b)(7) of this section.

(7) Agree that, if the hospital admits a case subject to preadmission review without certification, the case must receive retrospective prepayment review, according to the review priority established by the PRO.

§ 466.80 Coordination with Medicare fiscal intermediaries and carriers.

(a) *Procedures for agreements.* The Medicare fiscal intermediary or carrier must have a written agreement with the PRO. The PRO must take the initiative with the fiscal intermediary or carrier in developing the agreement. The following steps must be taken in developing the agreement.

(1) The PRO and the fiscal intermediary or carrier must negotiate in good faith in an effort to reach written agreement. If they cannot reach agreement, HCFA will assist them in resolving matters in dispute.

(2) The PRO must incorporate its administrative procedures into an agreement with the fiscal intermediary or carrier and obtain approval from HCFA, before it makes conclusive determinations for the Medicare program, unless HCFA finds that the fiscal intermediary or carrier has—

(i) Refused to negotiate in good faith or in a timely manner, or

(ii) Insisted on including in the agreement, provisions that are outside the scope of its authority under the Act.

(b) *Content of agreement.* The agreement must include procedures for—

(1) Informing the appropriate Medicare fiscal intermediaries and carriers of—

(i) Changes as a result of DRG validations and revisions as a result of the review of these changes; and

(ii) Initial denial determinations and revisions of these determinations as a result of ——— reconsideration and all approvals and denials with respect to cases subject to preadmission review and outlier claims in hospitals under a prospective payment system for health care services and items;

(2) Exchanging data or information;

(3) Modifying the procedures when additional review responsibility is authorized by HCFA; and

(4) Any other matters that are necessary for the coordination of functions.

(c) *Action of HCFA.* (1) Within the time specified in its contract, the PRO must submit to HCFA for approval its agreement with the Medicare fiscal intermediaries carriers, and if an agreement has not been established, the PRO's proposed administrative procedures, including any comments by

the Medicare fiscal intermediaries and carriers.

(2) If HCFA approves the agreement or the administrative procedures (after a finding by HCFA as specified in paragraph (a)(2) of this section), the PRO may begin to make determinations under its contract with HCFA.

(3) If HCFA disapproves the agreement or procedures, it will—

(i) Notify the PRO and the appropriate fiscal agents in writing, stating the reasons for disapproval; and

(ii) Require the PRO and fiscal intermediary or carrier to revise its agreements or procedures.

(d) *Modification of agreements.* Agreements or procedures may be modified, with HCFA's approval—

(1) Through a revised agreement with the fiscal intermediary or carrier, or

(2) In the case of procedures, by the PRO, after providing opportunity for comment by the fiscal intermediary or carrier.

(e) *Role of the fiscal intermediary.* (1) The fiscal intermediary will not pay any claims for those cases which are subject to preadmission review by the PRO, until it receives notice that the PRO has approved the admission after preadmission or retrospective review.

(2) A PRO's determination that an admission is medically necessary is not a guarantee of payment by the fiscal intermediary. Medicare coverage requirements must also be applied.

§ 466.82 Continuation of functions not assumed by PROs.

Any of the duties and functions under Part B of Title XI of the Act for which a PRO has not assumed responsibility under its contract with HCFA must be performed in the manner and to the extent otherwise provided for under the Act or in regulations.

§ 466.83 Initial denial determinations.

A determination by a PRO that the health care services furnished or proposed to be furnished to a patient are not medically necessary, are not reasonable, or are not at the appropriate level of care, is an initial denial determination and is appealable under Part 473 of this chapter.

§ 466.84 Changes as a result of DRG validation.

A provider or practitioner may obtain a review by a PRO under Part 473 of this chapter for changes in diagnostic and procedural coding that resulted in a change in DRG assignment as a result of PRO validation activities.

§ 466.85 Conclusive effect of PRO initial denial determinations and changes as a result of DRG validations.

A PRO initial denial determination or change as a result of DRG validation is final and binding unless, in accordance with the procedures in Part 473—

(a) The initial denial determination is reconsidered and revised; or

(b) The change as a result of DRG validation is reviewed and revised.

§ 466.86 Correlation of Title XI functions with Title XVIII functions.

(a) *Payment determinations.*

(1) PRO initial denial determinations under this part with regard to the reasonableness, medical necessity, and appropriateness of placement at an acute level of patient care as are also conclusive for payment purposes with regard to the following medical issues:

(i) Whether inpatient care furnished in a psychiatric or tuberculosis hospital meets the requirements of § 405.1629 of this chapter.

(ii) Whether payment for inpatient hospital or SNF care beyond 20 consecutive days is precluded under § 489.50 of this chapter because of failure to perform review of long-stay cases.

(iii) Whether the care furnished was custodial care or care not reasonable and necessary and, as such, excluded under § 405.310(g) or § 405.310(k) of this chapter.

(iv) Whether the care was appropriately furnished in the inpatient or outpatient setting.

(2) Reviews with respect to determinations listed in paragraph (a)(1) of this section must not be conducted, for purposes of payment, by Medicare fiscal intermediaries or carriers except as outlined in paragraph (c) of this section.

(3) PROs make determinations as to the appropriateness of the location in which procedures are performed. A procedure may be medically necessary but denied if the PRO determines that it could, consistent with the provision of appropriate medical care, be effectively provided more economically on an outpatient basis or in an inpatient health care facility of a different type.

(4) PRO determinations as to whether the provider and the beneficiary knew or could reasonably be expected to have known that the services described in paragraph (a)(1) of this section were excluded are also conclusive for payment purposes.

(b) *Utilization review activities.* PRO review activities to determine whether inpatient hospital or SNF care services

are reasonable and medically necessary and are furnished at the appropriate level of care fulfill the utilization review requirements set forth in §§ 405.1035, 405.1042, and 405.1137 of this chapter.

(c) *Coverage.* Nothing in paragraphs (a) (1) and (3) of this section will be construed as precluding HCFA or a Medicare fiscal intermediary or carrier, in the proper exercise of its duties and functions, from reviewing claims to determine:

(1) In the case of items or services not reviewed by a PRO, whether they meet coverage requirements of Title XVIII relating to medical necessity, reasonableness, or appropriateness of placement at an acute level of patient. However, if a coverage determination pertains to medical necessity, reasonableness, or appropriateness of placement at an acute level of patient care, the fiscal intermediary or carrier must use a PRO to make a determination on those issues if a PRO is conducting review in the area and must abide by the PRO's determination.

(2) Whether any claim meets coverage requirements of Title XVIII relating to issues other than medical necessity, reasonableness or appropriateness of placement at an acute level of patient care.

(d) *Payment.* Medicare fiscal intermediaries and carriers are not precluded from making payment determinations with regard to coverage determinations made under paragraph (c) of this section.

(e) *Survey, compliance and assistance activities.* PRO review and monitoring activities fulfill the requirements for compliance and assistance activities of State survey agencies under section 1804(a) with respect to sections 1861(e)(6), 1861(j)(8), 1861(j)(12), and 1861(k) of the Act, and activities required of intermediaries and carriers under §§ 421.100(d) and 421.200(f) of this chapter.

(f) *Appeals.* The requirements and procedures for PRO review of changes as a result of DRG validation and the reconsideration, hearing and judicial review of PRO initial denial determinations are set forth in Part 473 of this chapter.

§ 466.88 Examination of the operation and records of health care facilities and practitioners.

(a) *Authorization to examine records.* A facility claiming Medicare payment must permit a PRO or its subcontractor to examine its operation and records (including information on charges) that are pertinent to health care services furnished to Medicare beneficiaries and

are necessary for the PRO or its subcontractor to—

(1) Perform review functions including, but not limited to—

- (i) DRG validation;
- (ii) Outlier review in facilities under a prospective payment system; and
- (iii) Implementation of corrective action and fraud and abuse prevention activities;

(2) Evaluate cases that have been identified as deviating from the PRO norms and criteria, or standards; and

(3) Evaluate the capability of the facility to perform quality review functions under a subcontract with the PRO.

(b) *Limitations on access to records.* A PRO has access to the records of non-Medicare patients if—

(1) The records relate to review performed under a non-Medicare PRO contract and if authorized by those patients in accordance with State law; or

(2) The PRO needs the records to perform its quality review responsibilities under the Act and receives authorization from the facility or practitioner.

(c) *Conditions of examination.* When examining a facility's operation or records the PRO must—

(1) Examine only those operations and records (including information on charges) required to fulfill the purposes of paragraph (a) of this section;

(2) Cooperate with agencies responsible for other examination functions under Federal or Federally assisted programs in order to minimize duplication of effort;

(3) Conduct the examinations during reasonable hours; and

(4) Maintain in its principal office written records of the results of the examination of the facility.

§ 466.90 Lack of cooperation by a health care facility or practitioner.

(a) If a health care facility or practitioner refuses to allow a PRO to enter and perform the duties and functions required under its contract with HCFA, the PRO may—

(1) Determine that the health care facility or practitioner has failed to comply with the requirements of § 474.30(c) of this chapter and report the matter to the HHS Inspector General; or

(2) Issue initial denial determinations for those claims it is unable to review, make the determination that financial liability will be assigned to the health care facility, and report the matter to the HHS Inspector General.

(b) If a PRO provides a facility with sufficient notice and a reasonable amount of time to respond to a request

for information about a claim, and if the facility does not respond in a timely manner, PRO will deny the claim.

§ 466.93 Opportunity to discuss proposed initial denial determination and changes as a result of a DRG validation.

Before a PRO reaches an initial denial determination or makes a change as a result of a DRG validation, it must—

(a) Promptly notify the provider or supplier and the patient's attending physician (or other attending health care practitioner) of the proposed determination or DRG change; and

(b) Afford an opportunity for the provider or supplier and the physician (or other attending health care practitioner) to discuss the matter with the PRO physician advisor and to explain the nature of the patient's need for health care services, including all factors which preclude treatment of the patient as an outpatient or in an alternative level of inpatient care.

§ 466.94 Notice of PRO initial denial determination and changes as a result of a DRG validation.

(a) *Notice of initial denial determination—(1) Parties to be notified.* A PRO must provide written notice of an initial denial determination to—

(i) The patient, or if the patient is expected to be unable to comprehend the notice, the patient's next of kin, guardian or other representative or sponsor;

(ii) The attending physician, or other attending health care practitioner;

(iii) The facility; and

(iv) The fiscal intermediary or carrier.

(2) *Timing of the notice.* The notice must be delivered to beneficiaries in the facility or mailed to those no longer in the facility, within the following time periods—

(i) For admission, on the first working day after the initial denial determination;

(ii) For continued stay (e.g., outliers in facilities under a prospective payment system), by the first working day after the initial denial determination if the beneficiary is still in the facility, and within 3 working days if the beneficiary has been discharged;

(iii) For preprocedure review, before the procedure is performed;

(iv) For preadmission review, before admission;

(v) If identification as a Medicare program patient has been delayed, within three working days of identification;

(vi) For retrospective review, (excluding DRG validation and post procedure review), within 3 working

days of the initial denial determination; and

(vii) For post-procedure review, within 3 working days of the initial denial determination.

(3) *Preadmission review.* In the case of preadmission review, the PRO must document that the patient and the facility received notice of the initial denial determination.

(b) *Notice of changes as a result of a DRG validation.* The PRO must notify the provider and practitioner of changes to procedural and diagnostic information that result in a change of DRG assignment, within 30 days of the PRO's decision.

(c) *Content of the notice.* The notice must be understandable and written in plain English and must contain—

(1) The reason for the initial denial determination or change as a result of the DRG validation;

(2) For day outliers in hospitals, the date on which the stay or services in the facility will not be approved as being reasonable and medically necessary or appropriate to the patients' health care needs;

(3) A statement informing each party or his or her representative of the right to request in accordance with the provisions of Part 473, Subpart B of this chapter—

(i) Review of a change resulting from DRG validation; or

(ii) Reconsideration of the initial denial determination;

(4) The locations for filing a request for reconsideration or review and the time period within which a request must be filed;

(5) A statement about who is liable for payment of the denied services under section 1879 of the Act; and

(6) A statement concerning the duties and functions of the PRO under the Act.

(d) *Notice to payers.* The PRO must provide prompt written notice of an initial denial determination or changes as a result of a DRG validation to the Medicare fiscal intermediary or carrier within the same time periods as the notices to the other parties.

(e) *Record of initial denial determination and changes as a result of a DRG validation.* (1) The PRO must document and preserve a record of all initial denial determinations and changes as a result of DRG validations for six years from the date the services in question were provided.

(2) The documentary record must include—

(i) The detailed basis for the initial denial determination or changes as a result of a DRG validation; and

(ii) A copy of the determination or change in DRG notices sent to all parties

and identification of each party and the date on which the notice was mailed or delivered.

§ 466.96 Review period and reopening of initial denial determinations and changes as a result of DRG validation.

(a) *General timeframe.* A PRO or its subcontractor—

(1) Within one year of the date of the claim containing the service in question, may review and deny payment; and

(2) Within one year of the date of its decision, may reopen an initial denial determination or a change as a result of a DRG validation.

(b) *Extended timeframes.* (1) An initial denial determination or change as a result of a DRG validation may be made after one year but within four years of the date of the claim containing the service in question, if HCFA approves.

(2) A reopening of an initial denial determination or change as a result of a DRG validation may be made after one year but within four years of the date of the PRO's decision if—

(i) Additional information is received on the patient's condition;

(ii) Reviewer error occurred in interpretation or application of Medicare coverage policy or review criteria;

(iii) There is an error apparent on the face of the evidence upon which the initial denial or DRG validation was based; or

(iv) There is a clerical error in the statement of the initial denial determination or change as a result of a DRG validation.

(c) *Fraud and abuse.* (i) A PRO or its subcontractor may review and deny payment anytime there is a finding that the claim for service involves fraud or a similar abusive practice that does not support a finding of fraud.

(ii) An initial denial determination or change as a result of a DRG validation may be reopened and revised anytime there is a finding that it was obtained through fraud or a similar abusive practice that does not support a finding of fraud.

§ 466.98 Reviewer qualifications and participation.

(a) *Peer review by physician.* (1) Except as provided in paragraph (a)(2) of this section, each person who makes an initial denial determination about services furnished or proposed to be furnished by a licensed doctor of medicine or osteopathy or by a doctor of dentistry must be respectively another licensed doctor of medicine or osteopathy or of dentistry with active staff privileges in one or more hospitals in the PRO area.

(2) If a PRO determines that peers are not available to make initial denial determinations, a doctor of medicine or osteopathy may make denial determinations for services ordered or performed by a doctor in any of the three specialties.

(3) For purposes of paragraph (a)(1) of this section, individuals authorized to practice medicine in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands as "medical officers" may make determinations on care ordered or furnished by their peers but not on care ordered or furnished by licensed doctors of medicine or osteopathy.

(b) *Peer review by health care practitioners other than physicians.* Health care practitioners other than physicians may review services furnished by other practitioners in the same professional field.

(c) *DRG validation review.* Decisions about procedural and diagnostic information must be made by physicians. Technical coding issues must be reviewed by individuals with training and experience in ICD-9-CM coding.

(d) *Persons excluded from review.* (1) A person may not review health care services or make initial denial determinations or changes as a result of DRG validations if he or she, or a member of his or her family—

(i) Participated in developing or executing the beneficiary's treatment plan;

(ii) Is a member of the beneficiary's family; or

(iii) Is a governing body member, officer, partner, 5 percent or more owner, or managing employee in the health care facility where the services were or are to be furnished.

(2) A member of a reviewer's family is a spouse (other than a spouse who is legally separated under a decree of divorce or separate maintenance), child (including a legally adopted child), grandchild, parent, or grandparent.

§ 466.100 Use of norms and criteria.

(a) *Use of norms.* As specified in its contract, a PRO must use national, or where appropriate, regional norms in conducting review to achieve PRO contract objectives. However, with regard to determining the number of procedures selected for preadmission review, a PRO must use national admission norms.

(b) *Use of criteria.* In assessing the need for and appropriateness of an inpatient health care facility stay, a PRO must apply criteria to determine—

(1) The necessity for facility admission and continued stay (in cases of day outliers in hospitals under prospective payment);

(2) The necessity for surgery and other invasive diagnostic and therapeutic procedures; or

(3) The appropriateness of providing services at a particular health care facility or at a particular level of care. The PRO must determine whether the beneficiary requires the level of care received or whether a lower and less costly level of care would be equally effective.

(c) *Establishment of criteria and standards.* For the conduct of review a PRO must—

(1) Establish written criteria based upon typical patterns of practice in the PRO area, or use national criteria where appropriate; and

(2) Establish written criteria and standards to be used in conducting quality review studies.

(d) *Variant criteria and standards.* A PRO may establish specific criteria and standards to be applied to certain locations and facilities in the PRO area if the PRO determines that—

(1) The patterns of practice in those locations and facilities are substantially different from patterns in the remainder of the PRO area; and

(2) There is a reasonable basis for the difference which makes the variation appropriate.

§ 466.102 Involvement of health care practitioners other than physicians.

(a) *Basic requirement.* Except as provided in paragraph (b) of this section, a PRO must meet the following requirements:

(1) Consult with the peers of the practitioners who furnish the services under review of the PRO review care and services delivered by health care practitioners other than physicians.

(2) Assure that in determinations regarding medical necessity of services or the quality of the services they furnish, these practitioners are involved in—

(i) Developing PRO criteria and standards;

(ii) Selecting norms to be used; and

(iii) Developing review mechanisms for care furnished by their peers.

(3) Ensure that an initial denial determination or a change as a result of DRG validation of services provided by a health care practitioner other than a physician is made by a physician only after consultation with a peer of that practitioner. Initial denial determinations and changes as a result of DRG validations must be made only by a physician or dentist.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply if—

(i) The PRO has been unable to obtain a roster of peer practitioners available to perform review; or

(ii) The practitioners are precluded from performing review because they participated in the treatment of the patient, the patient is a relative, or the practitioners have a financial interest in the health care facility as described in § 466.98(d).

(c) *Peer involvement in quality review studies.* Practitioners must be involved in the design of quality review studies, development of criteria, and actual conduct of studies involving their peers.

(d) *Consultation with practitioners other than physicians.* To the extent practicable, a PRO must consult with nurses and other professional health care practitioners (other than physicians defined in 1861(r) (1) and (2) of the Act) and with representatives of institutional and noninstitutional providers and suppliers with respect to the PRO's responsibility for review.

§ 466.104 Coordination of activities.

In order to achieve efficient and economical review, a PRO must coordinate its activities (including information exchanges) with the activities of—

(a) Medicare fiscal intermediaries and carriers;

(b) Other PROs; and

(c) Other public or private review organizations as may be appropriate.

(Catalog of Federal Domestic Assistance Program No. 13.714, Medical Assistance Program; No. 13.773, Medical—Hospital Insurance; No. 13.774, Medicare—Supplementary Medical Insurance)

Dated: December 17, 1984.

Carolyn K. Davis,
Administrator, Health Care Financing Administration.

Approved: January 28, 1985.

Margaret M. Heckler,
Secretary.

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42 CFR Parts 405, 420, 474 and 489

[HSQ-109-F]

Medicare Program; Utilization and Quality Control Peer Review Organizations—Imposition of Sanctions on Health Care Practitioners and Providers of Health Care Services

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule implements the portion of the Peer Review Improvement Act of 1982 that imposes certain obligations on health care practitioners and other persons who provide health care services to Medicare beneficiaries. The rule also: (1) Establishes sanctions that the Secretary may impose for violations of the obligations; (2) imposes certain responsibilities on utilization and quality control peer review organizations; and (3) provides that an exclusion sanction will automatically become effective if the Secretary fails to act within a 120-day review period.

EFFECTIVE DATE: May 17, 1985. However, peer review organizations are not required to comply with the information collection requirements contained in §§ 474.36(b), 474.38(b), 474.38(c), 474.39(b), 474.40(b), and 474.40(c) until they are approved by the Office of Management and Budget. (See section VI.C. of the preamble for a discussion of the information collection requirements.)

FOR FURTHER INFORMATION CONTACT:

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(Department process), (301) 594-5035.

SUPPLEMENTARY INFORMATION:

I. Background

The Peer Review Improvement Act of 1982 (Title I, Subtitle C of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA, Pub. L. 97-248)) amended Part B of Title XI of the Social Security Act by establishing the Utilization and Quality Control Peer Review Organization (PRO) program. The PRO legislation, enacted on September 3, 1982, seeks to redirect, simplify, and enhance the cost-effectiveness of the peer review program under Medicare.

Section 143 of TEFRA amends sections 1151 through 1163 of the Social Security Act (the Act). As amended, section 1156 of the Act imposes certain obligations upon health care practitioners and other persons who furnish or order services under Medicare. Section 1156 of the Act also provides for sanctions if the Secretary determines that the obligations were not met. These sanctions are recommended to the Secretary by PROs that contract with the Secretary. PROs have the responsibility to determine whether practitioners and other persons are complying with their obligations under the statute. Based upon the PRO recommendations, the Secretary is authorized, by statute, to exclude practitioners or other persons from the

Medicare program or, in lieu of exclusion, require payment of a monetary penalty as a condition of continued eligibility to receive reimbursement under the program.

II. Discussion of Proposed Rule

On April 18, 1984, we published a proposed rule to implement section 1156 of the Act (49 FR 15233). Briefly, the major provisions of the proposal were as follows:

A. PRO Review Process

We proposed to require PROs to review activities of practitioners and other persons who furnish or order health care services or items and, when warranted, make determinations that obligations were violated and that corrective action is needed.

Under the proposal, when a practitioner or other person fails to comply substantially with an obligation in a substantial number of cases, or violates an obligation in a gross and flagrant manner, the PRO must report the violation to the Secretary. The Office of the Inspector General (OIG), Department of Health and Human Services, would act as the Secretary's designee.

The proposal detailed the procedures the PRO must follow in giving notice to the practitioner or other person and providing an opportunity for discussion before making a final determination that a practitioner or other person has violated an obligation. If, after following those procedures, the PRO still determines that a violation has occurred, the PRO would send its report and recommendations to the OIG.

The OIG would review the PRO report and either agree or disagree with the PRO's recommendations. If the OIG agrees with the PRO determination, it could exclude the practitioner or other person from the Medicare program, or in lieu of exclusion, require payment of a monetary penalty as a condition for continued participation in the program.

As provided in section 1156(b)(1) of the Act and our proposal, an exclusion would automatically become effective 120 days after a PRO recommendation for exclusion is received by the OIG, unless the OIG specifically rejects the recommendation. This provision would not apply to recommendations for a monetary penalty.

B. Effect of an Exclusion

Under the proposed rule, payment under Medicare would not be made to a practitioner or other person who has been excluded from the program for services or items furnished on or after the effective date of the exclusion. Also,

payment would not be made for services or items ordered by an excluded practitioner or other person. Further details of our proposal, and the rationale for the proposed policies may be found in the preamble to the April 18 document.

III. Analysis and Response to Comments

We received comments on the proposed rule from 52 commenters including individuals, hospitals, medical societies, hospital and other professional associations, and professional standards review organizations (PSROs). These comments and our responses to them are discussed below.

A. Comment Period

Comment: Some commenters believe that the comment period for the proposed regulations was too short. They stated that 30 days was not enough to address all the issues and implications adequately. The commenters also suggested that the deadline for PRO contracts be revised from October 1, 1984 to January 1, 1985 to allow more time for review and comment.

Response: We believe 30 days was adequate time for commenters to address the proposal. The comment period was limited to 30 days to allow HCFA ample time to review, analyze, and incorporate pertinent comments into the final rule. The initial date mandated by Congress for the implementation of the PRO program was October 1, 1984. The implementation date was subsequently extended to November 15, 1984 by the Deficit Reduction Act of 1984 (Pub. L. 98-369).

B. Definitions (§ 474.0(b))

Comment: One of the obligations of a health care practitioner or other person who furnishes or orders health care services under Medicare, is to assure that those services are furnished economically (proposed § 474.30(a)). The proposed rule stated that *economically* meant that services were provided at the least expensive, medically appropriate type of setting or level of care.

A few commenters suggested revisions to the definition of the term *economically*, stating that although a physician may agree that services could be provided at a lower level of care, that lower level may not exist or be available. In addition, commenters stated that the longer and more complicated inpatient stays should not be arbitrarily terminated because less intensive services could be given in another setting. They believe that, in

many cases, the continuity and completion of the patient care plan would be disrupted by such a move.

Other related comments on termination of stays cited the serious stress a patient could suffer, time wasted in the patient's physical transfer and transfer of medical records, and the adjustment problems the patient could have becoming familiar with new staff for a very short period of time.

Some commenters also suggested that the definition of *economically* should require transfer of a patient to another setting only when the new setting can actually take care of the patient. These commenters recommended that the definition be related to the availability of alternative settings or levels of care.

Response: We agree with the recommendation to revise the definition of *economically* and have added the word *available* to the definition. Thus, the requirement at § 474.30(a) that the practitioner provide services *economically*, means that the services must be provided at the least expensive, medically appropriate type of setting or level of care available. "Available", for this purpose, relates to the availability of alternative settings or levels of care with certain limitations (§ 405.1827). For example, if a patient no longer requires acute hospital care but could receive treatment, covered under Medicare, in a skilled nursing facility and there is no bed available to the patient, that continued stay in the hospital would be considered covered care. However, if a patient no longer needs an acute inpatient level of care but requires home health care services, any continued inpatient stay would not be considered covered care even though the necessary home health care services are not available. Consideration of alternatives by the PROs in no way implies any modification of current coverage policy.

Comment: One commenter believes that the definition of *economically* ignores the special needs of patients in rehabilitation hospitals and that the interpretation of the term *least expensive, medically appropriate type of setting or level of care* could cause significant problems. Another commenter stated that the proposed definition of *economically* could create the impression that the PRO or the physician is to make a comparative cost determination between institutional and other types of services. The commenter believes that this aspect should be clarified.

Response: The term *least expensive, medically appropriate* does not imply that a patient should be placed in or transferred to a facility or level of care

because the cost of the services needed is lower than in another similar facility (or level of care). The definition of *economically* for the final rule reads "least expensive, medically appropriate type of setting or level of care available". We believe this modified definition also addresses concerns related to special needs of patients in all types of settings.

Comment: Several commenters noted that the regulations do not define the criteria that PROs will utilize when making a determination that a practitioner or other person has (1) failed substantially to comply with any obligation in a substantial number of cases, or (2) grossly and flagrantly violated any obligation in one or more instances (§ 474.34(c)). Some commenters also stated that no definitions were given for *substantial* or *gross and flagrant* in the proposed rule. The commenters stated that without definitions, the interpretations will vary from one locality to another and even within a particular PRO area. The commenters believe that this will lead to inconsistent application of sanctions.

Response: We are not specifying the criteria for determining violations of the statutory obligations contained in section 1156(a) of the Act and § 474.30 of these final regulations. The PROs have responsibility for the review of the professional activities of practitioners or other persons. In rendering medical judgments, the PROs must apply, as principal points of evaluation and review, professionally developed norms of care, diagnosis, and treatment based on typical patterns of practice within the geographic area served by the organization. We agree with part of the comments and have added definitions for what will be considered *gross and flagrant* and *substantial* violations (§ 474.0(b)).

We have differentiated between *substantial* violation and *gross and flagrant* by interpreting the language used by the statute. *Substantial* violation in a substantial number of cases means a pattern of care has been provided that is inappropriate, unnecessary or does not meet the recognized professional standards of care or is not supported by the necessary documentation of care as required by the PRO. *Gross and flagrant* violation means a violation of an obligation has occurred in one or more instances which presents an imminent danger to health, safety or well being of a Medicare beneficiary or places the beneficiary unnecessarily in high risk situations.

Comment: One commenter suggests that the definition for Statewide Council

be deleted because Statewide Councils do not apply to the PRO program and are no longer operational in the PSRO program.

Response: We agree and have deleted the definition for Statewide Council.

C. Obligations of Practitioners or Other Persons (§ 474.30)

Comment: One commenter believes that the practitioner's or other person's obligation to assure that services are of a quality that meet professionally recognized standards of health care (proposed § 474.30(b)) could be a problem. The commenter states that a PRO may not be qualified to define these standards. Similarly, one commenter states that the proposed sanction process imposes the judgment of non-professionals on medical professionals without due process of law. A third commenter wants us to ensure that the sanction process is objective. This commenter is concerned that the proposed regulations could result in reviewers who are not familiar with certain procedures making arbitrary determinations of violations.

Response: The requirements and criteria for determining the capability of a PRO to perform medical review were specified in the request for proposal for PRO contracts. As part of the requirements, a PRO must have sufficient physician resources to conduct all required review activities. This requirement assures adequate peer review. The process followed in developing a sanction case under this regulation is very similar to the process used under the PSRO program. These procedures have been tested in court and found to be constitutionally sound.

Comment: Proposed § 474.30(c) stated that practitioners or other persons who furnish or order health care services under Medicare would be obligated to assure that the services are supported by evidence of medical necessity and quality in the form and fashion that the reviewing PRO may reasonably require. Some commenters believe that § 474.30(c) is not consistent with the related provision in the statute (section 1156(a)(3) of the Act). These commenters stated that this paragraph would require a hospital to substantiate its compliance with pre-admission or pre-procedure review requirements. They noted, however, that the request for proposal for PROs sent out by HCFA indicates that no review function except quality review studies will be delegated to a hospital by the PRO. The commenters believe, in essence, that the proposed rule would require hospitals to develop a system to comply with a review

activity that only the PRO is supposed to conduct.

Some commenters believe that the practitioner's or other person's obligation to comply with pre-admission or pre-procedure review requirements allows PROs to exercise a broad authority not supported by statute. They recommend that the reference to pre-admission and pre-procedure reviews be deleted from § 474.30(c). One commenter suggested that the pre-admission and pre-procedure reviews cited in § 474.30(c) should be performed on a delegated basis because this method would be the most cost-effective.

Response: The commenters are correct when they point out that no pre-admission or pre-procedure review activity will be delegated to hospitals and only the PROs will conduct this type of review. However, the intent of the requirement was misunderstood by the commenters and only needs to be clarified here. A PRO may require that practitioners or other persons follow certain procedures to enable the PRO to conduct this type of review, and all practitioners or other persons must comply. Hospitals must develop procedures to ensure that categories of patients subject to pre-admission review are, in fact, reviewed before admission. A violation of these procedures could result in a sanction. At its discretion, a PRO could request evidence of compliance with its review procedures to assure that a practitioner or other person is meeting the obligations imposed by section 1156(a) of the Act. Therefore, we do not believe that any changes are required in § 474.30(c).

Comment: Many commenters believe that PROs should not be provided with copies of medical records at the expense of the practitioner or other person (§ 474.30(c)). They stated that this provision shifts substantial unreimbursed costs to the practitioner or other person, causing an undue financial burden. One commenter noted that under the prospective payment system, the high non-reimbursable costs for retrieving, copying, and transporting records will result in higher charges to private pay patients.

Response: We believe it is important that PROs have adequate access to medical records to enable them to carry out required activities. This includes the right to request and receive copies as they deem necessary. In some cases, this will mean that the PRO will request hospitals to photocopy specific medical records and mail them to PRO. However, the cost of photocopying records is a hospital operating cost and,

as such, is covered by the DRG prospective payments.

The prospective payment rates are computed according to the provisions of the law and are also based on the best available data at the time of the computation. Administrative costs are included in the Federal and hospital specific portions of prospective payments by virtue of being incurred and reported by hospitals for the years that represent the data bases for the prospective payment system.

Prior to the use of PROs, review of inpatient hospital services was carried out either at the hospital or offsite. Offsite review sometimes required that the hospital mail patient records to Medicare fiscal intermediaries. These costs were subsumed in the hospital's administrative costs that in turn were reflected in Medicare cost reimbursement calculations. Costs related to such activities are accounted for, in some measure, in the prospective payment base rates.

We also believe that the fiscal benefits of PRO review will compensate for any such increased costs. For example, in many cases, PROs' pre-admission review activities will protect hospitals from many retrospective denials. Thus, there will be trade-offs between hospitals' costs of providing medical records to PROs and PROs' performance of review that in many cases, may assist hospitals in avoiding unnecessary expenditures.

Accordingly, we are not changing this section of the regulations.

D. Sanctions (§ 474.32)

Comment: One commenter stated that § 474.32(b) does not completely reflect the Act's provisions and limitations in section 11256(b)(3). The commenter believes that although the proposed rule reflects the fact that monetary penalties are to be imposed in lieu of exclusion and are limited to an amount not in excess of the cost of improper or unnecessary services, the proposed rule does not indicate that monetary penalties can be imposed only when "such acts or conduct involved the provision or ordering . . . of health care services which were medically improper or unnecessary."

Response: We agree and have modified § 474.32(b) to specifically state that penalty is only available in cases of unnecessary or improper services.

Comment: One commenter recommends that the time for payment of a monetary assessment be extended from six months to one year since the amount of the penalty may be substantial.

Response: We believe six months is a sufficient period of time for payment of any monetary assessment. The practitioner or other person will have an option of taking six months to pay the monetary assessment or having it deducted from any sums the Federal Government owes the practitioner or other person. We believe the six month period is appropriate given the basis for determining the amount of the penalty and the need to adequately monitor its enforcement.

Comment: One commenter states that HCFA should promote a means of coordinating sanction activity between the Medicare and Medicaid programs.

Response: We agree and are coordinating sanction activity to the extent that legislation allows notification to State agencies when sanctions are being imposed on practitioners and other persons participating in the Medicare program.

E. PRO Responsibilities (§ 474.34)

Comment: A commenter recommends that the regulations be amended to provide a means of accommodating the practitioner's or other person's comments prior to the PRO's identification of a violation. The commenter stated that before a PRO identifies a violation, the PRO should be required to speak with the practitioner or other person to obtain his or her view of the facts and to see if a mutually satisfactory resolution could be reached.

Response: We agree with the comments but have not accepted the recommendation to revise the proposed rule because the requirements suggested are beyond the scope of the regulations and have already been included in the peer review plan of the PRO. A PRO must use all appropriate mechanisms of review and intervention to resolve adverse situations and assure compliance with the statutory obligations prior to using the sanction procedures specified in these final regulations. The sanction process is viewed as a measure of last resort in the peer review program. We believe that the broad scope of the basic responsibilities addressed in § 474.34(a) applies to the requirement of resolving situations before using the sanction procedures under this final rule.

Comment: Proposed § 474.34(e) requires the PRO to deny Medicare payment for services or items ordered by an excluded practitioner or other person when the PRO identifies such services or items and reports the findings to HCFA. One commenter stated that it will be almost impossible for a PRO to identify items or services ordered by an excluded practitioner

from another area or State, given the present state-of-the-art for tracking excluded practitioners. The commenter suggested that § 474.34(e) be modified to recognize this difficulty.

Response: We have not changed this section because we believe that the provisions requiring that notice of sanction be provided to the PRO who originated the sanction report and PROs in adjacent areas (as defined in § 474.52(e) (1) and (2)) reduce the potential difficulty that may be encountered by a PRO in identifying services or items ordered by an excluded practitioner. Section 474.34(e) does not require a tracking mechanism for an excluded practitioner outside the jurisdiction of a PRO. However, PROs are statewide organizations and are expected to conduct statewide monitoring. The OIG's internal procedures requiring monthly notice of sanctioned individuals to every State and PRO could facilitate the identification of an out-of-State practitioner who could be furnishing services in another State.

F. Action of Identification of a Violation (§ 474.36)

Comment: One commenter stated that § 474.36(b), concerning PRO action if the PRO determines that a violation is a substantial failure to comply in a substantial number of cases, should require the PRO to send the practitioner or other person a written initial notice when the PRO identifies the violation.

Response: We agree with this comment and have clarified the section to require the PRO to send a written notice when a substantial violation is identified.

Comment: One commenter believes that a summary of the information used by the PRO in arriving at its determination (which is supplied to the practitioner or other person at the time a violation is identified) is insufficient to support action by the PRO at that time. The commenter believes that the practitioner or other person would be unable to respond properly to the PRO's allegations, unless detailed supporting material were provided at the time of notice.

Response: We believe the summary information that the PRO provides with the written notice at the time a substantial violation is identified is adequate. This summary must be complete enough to advise the physician or other person of the issues involved and to identify the significant information on cases used in determining the violation. Section 474.38(b) requires the PRO to provide a

copy of all the material used by the PRO if it is determined that a violation has, in fact, occurred.

G. PRO Determination of a Violation (§ 474.39)

Comment: The proposed regulations allow a practitioner or other person 20 or 30 days to respond to PRO notices during different stages of the sanction process (§§ 474.36(b)(6), 474.38(b)(5), and 474.39(b)(2)). Various commenters stated that 20 or 30 days is not enough time for a reasonable reply. One commenter also noted that the failure of a PRO to release notices in a timely manner and potential delays in the postal system could limit the available time even more. The commenters suggested that: (1) The time frames be extended by 10 or 15 days, (2) practitioners or other persons be given 20 to 30 days to reply from the date the PRO notification is received, and (3) only work days be considered in the time frames.

Response: Sections 474.36(b)(6), 474.38(b)(5), and 474.39(b)(2) have been modified to incorporate the suggestion that practitioners or other persons be given 20 or 30 days, as specified, to reply from the date the PRO notification is received. The date of receipt is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary. We are not further extending these timeframes for the final rule. These timeframes have been extended already from the time allowed under the previous sanction regulations. Extending the timeframes any longer would prolong an already lengthy process. We believe that the time allowed is adequate for a practitioner or other person to respond.

Comment: We proposed that if the issue concerning the PRO's determination of a violation is not resolved to the PRO's satisfaction, the PRO would submit its report and recommendation to the OIG, and the practitioner or other person would have 30 days to submit additional material to the OIG. One commenter recommends that the proposal be revised to allow the OIG to accept information beyond the proposed 30-day period if the practitioner or other person has exercised diligence in providing or obtaining information, and acceptance of the information could materially affect the outcome of the case.

Response: We believe the time limits specified in the regulations are sufficient for the practitioner or other person to submit additional material to the OIG. Additionally, in view of the statutory mandate that the Secretary act within

120 days of the receipt of a PRO recommendation for exclusion, the granting of any additional time in which to submit additional information would interfere with the OIG responsibility in this regard.

H. PRO Report to OIG (§ 474.40)

Comment: One commenter states that the language contained in § 474.40(c)(4) was merely repetitive of the language in the statute and requested a more thorough explanation as to how a "finding" could be made as to whether a practitioner or other person is unable or unwilling substantially to comply with his or her obligations.

Response: We have changed the word "finding" to "recommendation" in § 474.40(c)(4). Section 1156(b) of the Act requires the Secretary, rather than the PRO, to make the determination before invoking a sanction, that the practitioner or other person is unable or unwilling substantially to comply with the statutory obligations. We have not specified the information that the PRO must use in making its recommendation in the final regulation. The PROs are responsible for determining in each situation the information that would best support their recommendation. For example, the PRO could base its recommendation on the experience the PRO has had with the particular practitioner as well as any other information considered relevant by the PRO.

I. Basis for Recommended Sanction (§ 474.41)

Comment: Proposed § 474.41 contains the various considerations on which the PRO would base its recommendations for a specific type of sanction. A commenter stated that two of the listed considerations were duplicative, and that we should require consideration of the availability of alternative sources of services in the community.

Response: The repetition was due to a typographical error that has been corrected in these final regulations. The proposal should have required, in place of the duplication, a consideration of the deterrent value of the sanction. Also, the commenter's request concerning alternative sources of services in the community has been accepted. However, as discussed in section III.B. of this preamble, consideration of alternatives by the PROs in no way implies any modification of current coverage policy.

J. Review of PRO Report by the OIG (§ 474.42)

Comment: One commenter suggests that § 474.42(b) should be revised to

expand the bases for OIG review of a PRO's report and recommendations to include, in the case of evidentiary violations, whether the PRO's procedures and demands for documentation in the cases at issue were reasonable and necessary to performance of its duties under the Act.

Response: We believe the requirement contained at § 474.42(b)(1) that the OIG determine whether the PRO is following its procedures is sufficient to substantiate whether the PRO's actions were reasonable and necessary.

Comment: One commenter noted that paragraphs (d) through (f) of § 474.42 were incorrectly designated since paragraph (c) was omitted.

Response: Appropriate redesignations have been made to correct the typographical error.

Comment: One commenter stated that § 474.42(e) (2) and (3) [redesignated in this final rule as paragraphs (d) (2) and (3)] were not clear as to how the type and severity of offense would be classified and weighed in the OIG's sanction determination.

Response: We believe the present language adequately advises the reader of the manner in which the OIG determines the appropriateness of any sanction. Identical language was found in former § 474.10, relating to HCFA's deliberations concerning the imposition of a sanction following the receipt of a PSRO report.

Comment: Many commenters disagree with the automatic imposition of an exclusion if the OIG (acting as the Secretary's designee) does not act within the 120-day review period (proposed § 474.42(f)). These commenters believe that this is an arbitrary intrusion into the Secretary's discretionary role that fails to consider special circumstances that may arise. The commenters want some action required by the OIG before an exclusion could be effective. One commenter stated that the automatic exclusion is inappropriate because action by the OIG is required to reinstate a practitioner or other person in the Medicare program.

Response: We are unable to accept these comments because the 120-day provision for the automatic implementation of an exclusion is required by section 1156(b)(1)(B) of the Act. However, if an exclusion sanction becomes effective because a decision was not made within 120 days, the OIG will complete the review of the case and issue a notice to the practitioner or other person affirming or modifying the PRO recommendation. We would note that proposed § 474.42(f) has been

redesignated as § 474.42(e) in this final rule.

Comment: Several comments were received concerning the imposition of a monetary penalty in lieu of an exclusion. Specifically, the proposed rule states that the 120-day provision for automatic imposition does not apply to the recommendations for a monetary penalty. Commenters requested specific language to reflect the appropriate handling of monetary penalty recommendations, specifying the action that OIG will take in these cases.

Response: We have modified the section pertaining to the automatic imposition of an exclusion to accommodate the comments. We have also added a new paragraph (§ 474.42(f)) relating to monetary penalty recommendations to address the comments.

K. Notice of Sanction (§ 474.52)

Comment: In the case of an exclusion under the proposed rule, the OIG would specify the earliest date on which it would accept a request for reinstatement. One commenter believes that the OIG should consider reinstatement of a practitioner without inflexible time limits when to do so would serve the interest of patients and the program.

Response: Under current HCFA regulations in 42 CFR Part 420—Program Integrity, § 420.132, Criteria for Action on Request for Reinstatement, provides that reinstatement will not be granted unless it is reasonably certain that the violations that led to exclusion will not be repeated. Statutory authority is given to the Secretary to exclude either permanently or for such period as may be determined. By excluding for a specific period of time, the practitioner or other person will have sufficient time to improve his or her medical practice or services and to demonstrate to the Secretary that the violations that led to exclusion will not recur. Furthermore, allowing reinstatement prior to the period specified by the Secretary would mitigate against the effect of imposing a sanction. To permit the practitioner or other person to apply for reinstatement when the practitioner or other persons believes that he or she is ready to be reinstated would be totally unmanageable and would not be of benefit to the program. This could allow the person to apply one week after the effective date.

Comment: Many commenters are concerned that the new regulations do not adequately address the administrative appeals process available to a practitioner or other

person who receives a sanction notice from the OIG.

Response: Several modifications have been made to accommodate these concerns. We have added a new paragraph (g) to § 474.52 to specify that the OIG's determination and notice of sanction under these regulations constitute an "initial determination" and a "notice of initial determination" for purposes of the administrative appeals process. These initial determinations are not subject to reconsideration. Instead, if dissatisfied with an initial determination, a practitioner or other person must request a hearing. We have revised § 474.56 to clarify that the OIG's determination that the basis for the exclusion no longer exists and that there is reasonable assurance that the problems will not recur must be made in accordance with 42 CFR 420.130–420.136. We have also revised § 474.58 to clarify that a practitioner or other persons dissatisfied with the OIG's determination or an automatic exclusion sanction is entitled to a hearing before an Administrative Law Judge and may also request a review of that decision by the Appeals Council in accordance with 42 CFR 405.1530 through 405.1595 of this chapter.

Comment: Many commenters strongly believe that, since hospitals and other health care providers could potentially be held liable for services ordered by the sanctioned practitioner, the OIG should notify hospitals and other health care providers where the sanctioned practitioner may be practicing.

Response: We agree, in part, with these comments, and have added a requirement to § 474.52(e)(5) that notifications be given to the hospital where the sanctioned individual's case originated and where the individual currently has privileges, if known.

L. Effect of an Exclusion on Medicare Payments and Services (§ 474.54)

Comment: Many commenters noted that under § 474.54(a)(2) providers will not be paid for items or services ordered by the excluded practitioner or other person even though the provider may not be aware of the exclusion. These commenters believe that a provider (especially the institutions where the practitioner practices) must get adequate notice of sanction if the provider is going to be held liable in this manner. The commenters stated that the provision, as proposed, imposes an undue financial burden on providers because they will not be aware of particular sanctions.

Response: As previously noted, we will notify the hospital where the sanctioned individual's case originated

and where the individual currently has visiting privileges, if known.

Comment: We proposed to continue payment for inpatient hospital or skilled nursing services for 30 days after the effective date of an exclusion, for services furnished to a beneficiary who was admitted before the effective date of the exclusion. One commenter questioned why the length of stay should be determined by a sanction when a patient's admission is found to be medically necessary and appropriate (§ 474.54(b)(1)). This commenter noted that the prospective payment system already has sufficient remedies for lengths of stay and total costs that exceed the designated limits. The commenter believes that the hospitals should receive payment for items and services covered by the Medicare program and found by the PRO to be provided appropriately, regardless of the relationship of the length of stay to the effective date of the sanction.

Response: This is a statutory requirement contained in section 1866(b)(3) of the Act, and we cannot revise that policy in § 474.54(b)(1). Although we received no comments related to the payment exception for home health services or items, we have modified § 474.54(b)(2) to reflect a recent change to the Act that was contained in section 2348 of the Deficit Reduction Act of 1984 (Pub. L. 98-369). That statutory revision amended section 1866(b)(4) of the Act to permit payment for home health services or items furnished under a plan established before the effective date of exclusion to be available for services or items furnished up to 30 days after the effective date.

M. Hearings and Appeals (§ 474.58)

Many commenters are concerned about the hearings and appeals that would be available under the proposed regulations. The following comments illustrate these concerns.

Comments:

- The proposed sanction process deprives practitioners or other persons of their constitutionally guaranteed right to legal counsel and judicial proceedings prior to the imposition of a sanction.

- An individual practitioner's reputation in the community could be irreparably damaged by an incorrect finding and publication of a sanction. All alleged violators should be accorded the right to a full, fair, and impartial evidentiary hearing prior to the imposition of a sanction and public disclosure. Publication of a sanction should be postponed until appeals are

completed, or until the time to appeal has expired.

- There is no opportunity to appeal a substantive error during the period that the OIG is reviewing the PRO's determination.

- Sections 474.36 and 474.38 of the proposed regulations (PRO identification and determination of a violation) should be revised. The regulations do not provide for an evidentiary hearing, permit the alleged violator to cross-examine witnesses or call witnesses in its defense, nor provide for an objective forum to judge the PRO's determination. Under the proposed regulations, the PRO would determine that a violation exists and then would judge whether or not the determination is correct.

- The practitioner or other person should have at least as much time to develop its documentation as the PRO took in preparing the determination of a violation.

- The regulations preclude any meaningful administrative review. Proposed § 474.52 provides that a sanction would be effective 15 days after the practitioner or other person is notified. A sanction could be entered, imposed, publicized, and implemented before the practitioner or other person has had any hearing and before there has been any opportunity to be heard by an independent forum. The regulations should provide that a sanction will not go into effect before a provider has had an opportunity to exhaust administrative review rights and not until one month after any petition for judicial review is filed.

- The regulations should require the PRO to provide the practitioner or other person with the actual information used by the PRO to determine that a violation exists. The summary of information (§ 474.38(b)(7)) required in the proposed regulations is not sufficient for a practitioner or other person to prepare an adequate defense.

- The regulations do not provide the practitioner or other person with a hearing before the OIG. While § 474.39(b)(2) grants the right to submit additional material to the OIG, it does not allow critical activities such as the right to cross-examine and probe the data upon which the PRO has relied.

Response: We do not agree that a formal hearing is required before implementation of a sanction.

Section 1156(c) of the Act provides for a hearing and judicial review as provided in section 205(b) and (g) of the Act, respectively. In accordance with these sections, the hearing and judicial review of administrative determinations do not occur before the decision is implemented.

Provision has been made in the regulations for an opportunity for the practitioner or other person to submit additional documentary evidence or written argument to the OIG before any sanction is imposed. This information must be submitted within 30 days from the date of receipt of final notice of a violation (§ 474.39(b)). We believe that the two opportunities to meet with the PRO in the case of a substantial violation (one opportunity in a gross and flagrant situation) before a final determination of a violation is made, and the opportunity to submit additional written argument or evidence to the OIG prior to its determination, along with the opportunity for an evidentiary hearing and judicial review after the implementation of a sanction, fully satisfy the due process standards as set forth by the United States Supreme Court in *Matthews v. Eldridge*, 424 U.S. 319 (1976).

In the *Eldridge* case, the Supreme Court made clear that due process does not require a full evidentiary pretermination hearing. The Court in the *Eldridge* case set forth three factors to be evaluated in deriving specific requirements of due process for a given situation:

- (a) The private interest involved;
- (b) The reliability of the process in making correct determinations and the probable value of additional safeguards; and
- (c) The government's interest, including the fiscal and administrative burdens of additional safeguards (424 U.S. at 335).

The private interest here concerns practitioners' or providers' abilities to furnish services for which payment may be made under the Medicare program. Continued access to Medicare funds is not a prerequisite for the practitioner or provider continuing to furnish health care services to patients but concerns the physicians' access to one group of potential customers for their services. The government's interest, on the other hand, is not only fiscal but also the health and safety of individuals who are eligible for Medicare benefits.

In our view, the meeting with the PRO before it files a sanction report, and then the opportunity to provide additional written evidence or argument to the OIG before a determination is made, assures a high degree of reliability for the OIG's actions and safeguards against the erroneous imposition of a sanction.

We believe that requiring a full evidentiary hearing prior to the OIG's actions would not only be contrary to the Act but would adversely affect the health and safety of individuals. It also would add to the OIG's administrative

and fiscal burdens by precluding prompt action and by allowing the continuation of benefit payments pending a conclusion of the hearing, without adding significantly to the reliability of the OIG's decision.

IV. Summary of Changes to the Proposed Rule

The following summary of regulations changes is provided for the reader's reference.

1. Section 405.1502

- We have added a new paragraph (f) to specify that the determination and notice of sanction under the PRO program is one of the initial determinations made by the Secretary.

2. Section 405.1503

- This section has been revised to distinguish between the notification procedures for initial determinations under the PRO sanction process and the notification procedures for other types of initial determinations.

3. Section 420.115(c)

- This paragraph has been revised to reflect a recent statutory change contained in section 2348 of Pub. L. 98-369. The statutory change provides that Medicare payment may be made for certain services furnished up to 30 days after the date of termination from the Medicare program.

4. Section 420.126(e)

- This paragraph has also been revised to reflect the recent statutory change contained in section 2348 of Pub. L. 98-369. The statutory change provides that Medicare payment may be made for certain services furnished up to 30 days after the date of termination from the Medicare program.

5. Section 474.0(a)

- The reference to Statewide Councils has been deleted from paragraph (a)(2).

6. Section 474.0(b)

- The definition of *economically* has been revised to clarify that the appropriate level of care is a level of care that is actually available.

- A definition for *gross and flagrant violation* has been added.

- A definition for *substantial violation* has been added.

- The definition for *Statewide Council* has been deleted.

- The definitions for *PRO* and *PSRO* have been deleted because the terms are already defined in Part 400, § 400.200 General definitions.

7. Section 474.36(b)

• The term *substantial failure to comply* has been changed to read a *substantial violation in a substantial number of cases*.

• We have clarified that the PRO's notice to the practitioner or other person must be in writing.

8. Sections 474.36(b)(6), 474.38(b)(5), and 474.39(b)(2)

• These sections have been revised to specify that the practitioner's or other person's time to respond to the PRO notice begins on the date the PRO notice is received. Further, the date of the receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary.

9. Section 474.40(c)(4)

• The word *finding* has been changed to *recommendation* to clarify that the PRO makes a recommendation and not a determination concerning the practitioner's or other person's ability to comply with an obligation that was violated.

10. Section 474.41

• The typographical error in paragraph (c) of the proposed rule has been corrected by adding the statement originally intended.

• A new paragraph (e) has been added to recognize that a PRO must consider the availability of alternative sources of service in the community when deciding whether to recommend a sanction.

• Paragraph (e) of the proposed rule has been redesignated as paragraph (f) in this final rule.

11. Section 474.42

• To correct a typographical error in the proposed rule, paragraphs (d), (e), and (f) have been redesignated as paragraphs (c), (d), and (e), respectively.

• Paragraph (e) has been revised to clarify the provisions concerning an automatic exclusion sanction.

• A new paragraph (f) has been added to clarify the provisions concerning a monetary penalty.

12. Section 474.52

• Paragraph (e)(5) has been revised to clarify that a notice of sanction will be provided to the hospital where the sanctioned individual has privileges and to the hospital where the case originated, if known.

• Paragraph (f) of the proposed rule has been revised to clarify the notification procedures when an automatic exclusion sanction is involved.

• A new paragraph (g) has been added to clarify that the determination and notice of sanction constitute an initial determination and a notice of initial determination for purposes of administrative appeals procedures.

13. Section 474.54(b)

• This paragraph has been revised as required by section 2348 of Pub. L. 98-369. The statute provides that Medicare payment may be made for certain services furnished up to 30 days after the date of termination from the Medicare program.

14. Section 474.56(a)

• This paragraph has been revised to clarify that the OIG must comply with §§ 420.130 through 420.136 when deciding whether an exclusion sanction should be terminated.

15. Section 474.58(a)

• This paragraph was revised to clarify the practitioner's or other person's appeal rights.

16. Section 489.55

• This section was also revised to reflect a change contained in section 2348 of Pub. L. 98-369. The statutory change provides that Medicare payment may be made for certain services furnished up to 30 days after the date of termination from the Medicare program.

17. Miscellaneous changes

• We have made numerous minor editorial and technical revisions to clarify and correct the language in the regulations and to provide easier reading. All regulations sections contain one or more of these types of revisions.

18. Conforming changes

• Sections 405.1504, 405.1530, and 405.1531 have been revised to include a cross-reference to new § 405.1502(f).

V. Waiver of Notice of Proposed Rulemaking for Certain Sections

The revisions in §§ 420.115(c), 420.126(e), 474.54(b), and 489.55 are conforming changes made necessary by section 2348 of Pub. L. 98-369. This statutory provision became effective on July 18, 1984, the date of enactment of Pub. L. 98-369. Our conforming changes are being issued as part of this final rule because the effective date of the provision was statutorily mandated and because the provision itself is self-implementing.

The conforming changes do not expand upon the statutory provision, but merely paraphrase it. Accordingly, we find that a notice of proposed rulemaking for the conforming changes

would be impractical and unnecessary, and find good cause to waive it.

VI. Impact Analyses

A. Executive Order 12291

Executive Order 12291 requires that a regulatory impact analysis be performed for any "major" regulation; that is, a regulation that will result in an economic impact of \$100 million or more, or a regulation that meets other criteria specified in section 1(b) of the Order.

Under these final regulations, a PRO can recommend certain sanctions to the OIG when a practitioner or other person fails to meet obligations specified at section 1156(a) of the Act.

The PRO can recommend exclusion or, in lieu of exclusion, the assessment of a monetary penalty. An exclusion will become effective automatically 120 days after a PRO submits a recommendation for exclusion to the OIG, if a decision is not made within the 120-day period. This does not represent a major change from our current sanction activities. Although these regulations will expedite the review and completion of sanction cases, the incremental impact of these regulations will be negligible.

In this final rule, we are also clarifying and revising certain provisions of the proposed rule to accommodate questions and issues raised by numerous commenters. Taken as a whole, these changes are not significant departures from our current policies and procedures. Therefore, we have determined that a regulatory impact analysis is not required because these regulations do not meet the criteria for a "major" regulation.

B. Regulatory Flexibility Act

We do not expect these regulations to cause a significant incremental increase in our sanction activity. Historically, we have imposed administrative sanctions only in particularly abusive situations. Therefore, we believe that these sanction regulations will affect relatively few practitioners or other persons. Accordingly, we have determined that these regulations will not result in a significant impact on a substantial number of providers and practitioners.

Therefore, the Secretary certifies under 5 U.S.C. 605(b), as enacted by the Regulatory Flexibility Act of 1980 (Pub. L. 96-354), that these regulations will not result in a significant impact on a substantial number of small entities.

C. Reporting and Recordkeeping Requirements

Sections 474.36(b), 474.38(b), 474.38(c), 474.39(b), 474.40(b), and 474.40(c) contain information collection requirements to which PROs must adhere. We are submitting the requirements in these regulations to the Office of Management and Budget (OMB) for review under the requirements of the Paperwork Reduction Act of 1980 (Pub. L. 96-511). PROs are not required to comply with these information collection requirements until OMB approves them. Comments on these requirements should be sent directly to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, Washington, D.C., Attention: Fay Iudicello. A notice will be published in the *Federal Register* when approval is obtained.

VII. LIST OF SUBJECTS

42 CFR Part 405

Administrative practice and procedure, Certification of compliance, Clinics, Cost-based reimbursement, Contracts (Agreements), End-Stage Renal Disease (ESRD), Health care, Health facilities, Health maintenance organizations (HMO), Health professions, Health suppliers, Home health agencies, Hospitals, Inpatients, Kidney diseases, Laboratories, Medicare, Nursing homes, Onsite surveys, Outpatient providers, Reasonable charges, Reporting and recordkeeping requirements, Rural areas, Prospective payment system, X-rays.

42 CFR Part 420

Abuse, Administrative practice and procedure, Contracts (Agreements), Conviction, Convicted, Courts, Exclusion, Fraud, Health care, Health facilities, Health maintenance organizations (HMO), Health professions, Health suppliers, Information (Disclosure), Lawyers, Medicaid, Medicare, Penalties, Professional Standards Review Organizations (PSRO), Reporting and recordkeeping requirements, Supervision.

42 CFR Part 474

Health care, Health professions, Penalties, Professional Standards Review Organization (PSRO), Reporting and recordkeeping requirements, Sanctions, and Utilization and Quality Control Peer Review Organization (PRO).

42 CFR Part 489

Clinics, Health care, Health facilities, Medicare, Provider Agreements, Rural health clinics, Termination procedures. 42 CFR Chapter IV is amended as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

A. Part 405 is amended as follows:

1. The authority citation for Subpart O is revised to read as follows:

Authority: Secs. 1102, 1866, 1869, 1871, and 1872 of the Social Security Act; 42 U.S.C. 1302, 1395cc, 1395ff, 1395hh, and 1395il, unless otherwise noted.

2. The introductory paragraph for § 405.1502 is reprinted unchanged and the section is amended by adding a new paragraph (f) to read as follows:

§ 405.1502 Initial determinations.

The Secretary will make findings setting forth the pertinent facts and conclusions, and an initial determination with respect to:

(f) The determination and notice of sanction provided for in §§ 474.52(a) and 474.52(g) of this chapter.

3. Section 405.1503 is revised to read as follows:

§ 405.1503 Notice of initial determinations.

A written notice of an initial determination as specified in paragraphs (a) through (f) of § 405.1502 will—

(a) Be mailed to the concerned provider, supplier, or practitioner; and
(b) Include the basis or reasons for the determination, and information concerning appeal rights. (See § 405.1510 concerning the right to a reconsideration, if applicable, and § 405.1530 concerning the right to a hearing.)

4. Section 405.1504 is revised by adding a cross-reference to § 405.1502(f) to read as follows:

§ 405.1504 Effect of initial determination.

The initial determination shall be final and binding upon the parties to the determination unless: (a) It is revised (see § 405.1519); (b) in the case of a determination described in § 405.1502 (a), (b)(1), or (d)(1), it is reconsidered in accordance with § 405.1514; or (c) in the case of a determination described in § 405.1502 (b)(2), (c), (d)(2), (e), or (f), a request for a hearing is filed and the initial determination is reversed.

5. Section 405.1530 is revised by adding a cross-reference to § 405.1502(f) to read as follows:

§ 405.1530 Hearing: Right to hearing.

After an initial and reconsidered determination described in §§ 405.1502 (a), (b)(1), (d)(1), and 405.1514; or after an initial determination described in § 405.1502 (b)(2), (c), (d)(2), (e), or (f); or after a revised determination described in § 405.1519, an institution, agency, clinic, laboratory, portable X-ray supplier, ambulatory surgical center, end-stage renal disease treatment facility, or person shall be entitled to a hearing with respect to such determination, if such person or the representative of the institution, agency, clinic, laboratory, portable X-ray supplier, ambulatory surgical center, end-stage renal disease treatment facility, or person files a written request for hearing as provided in § 405.1531.

6. Section 405.1531(a) is revised by adding a cross-reference to § 405.1502(f) to read as follows:

§ 405.1531 Filing a request for a hearing: time and manner of filing.

(a) The request for a hearing shall be made in writing, signed by the person, or a proper official of the institution, agency, clinic, laboratory, portable X-ray supplier, ambulatory surgical center, or end-stage renal disease treatment facility concerned and filed at an office of the Department of Health and Human Services, or with a presiding officer of the Appeals Council of the Office of Hearings and Appeals. The request must be filed within 60 days after the date notice of an initial determination provided for in § 405.1502 (b)(2), (c), (d)(2), (e), or (f); or a reconsidered or revised determination, is received by the institution, agency, clinic, laboratory, portable X-ray supplier, ambulatory surgical center, end-stage renal disease treatment facility, or person (see §§ 405.1503, 405.1516, and 405.1520), except where the time is extended for "good cause" (see § 405.1569). For purposes of this section, the date of receipt of notice of the initial, reconsidered or revised determination shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary.

PART 420—PROGRAM INTEGRITY

B. Part 420 is amended as follows:

1. The authority citation for Part 420 continues to read as follows:

Authority: Secs. 1102, 1862(d) (1), (2), (3), and (4), 1862(e), 1866(b) (2)(D), (E), and (F), 1871, 1902(a)(39), and 1903(i)(2) of the Social Security Act (42 U.S.C. 1302, 1395y(d), 1395cc, 1395hh, 1396a, and 1396b, unless otherwise noted).

2. Section 420.115(c) is revised to read as follows:

§ 420.115 Effect of exclusion.

(c) *Exceptions.* Payment is available for up to 30 days after the effective date of exclusion for—

(1) Inpatient hospital services or posthospital skilled nursing facility care services furnished to a beneficiary who was admitted to a hospital or a SNF before the effective date of exclusion; and

(2) Home health services furnished under a plan established before the effective date of exclusion.

3. Section 420.126(e) is revised to read as follows:

§ 420.126 Effect of suspension.

(e) *Exceptions.* Payment is available for up to 30 days after the effective date of the suspension for—

(1) Inpatient hospital services or posthospital skilled nursing facility care furnished to a beneficiary who was admitted to a hospital or a SNF before the effective date of the suspension; and

(2) Home health services furnished under a plan established before the effective date of the suspension.

PART 474—IMPOSITION OF SANCTIONS ON HEALTH CARE PRACTITIONERS AND PROVIDERS OF HEALTH CARE SERVICES

C. Part 474 is amended as follows:

1. The table of contents and the authority statement are revised to read as follows:

Subpart A—General Provisions

Sec.

474.0 Scope and definitions.

Subpart B—Sanctions Under the PSRO Program

474.1 Statutory obligations of practitioners and providers.

474.2 Sanctions.

474.3 PSRO responsibilities.

474.4 Action on potential violation.

474.5 Factors in PSRO determination of a violation.

474.6 Basis for recommended sanction.

474.7 Notice and review of PSRO determination of violation.

474.8 PSRO report to the Statewide Council or to HCFA.

474.9 Role and functions of the Statewide Council.

474.10 Action by HCFA on receipt of the report.

474.14 Effective dates of exclusion.

474.15 Reinstatement after exclusion.

474.17 Right to judicial review.

Subpart C—Sanctions under the PRO Program: General Provisions

474.30 Statutory obligations of practitioners and other persons.

474.32 Sanctions.

Subpart D—PRO Responsibilities

474.34 Basic responsibilities.

474.36 Action on identification of a violation.

474.38 Action on determination of a violation.

474.39 Final PRO determination of a violation.

474.40 PRO report to OIG.

474.41 Basis for recommended sanction.

Subpart E—OIG Responsibilities

474.42 Acknowledgment and review of report.

474.52 Notice of sanction.

Subpart F—Effect and Duration of Exclusion

474.54 Effect of an exclusion on Medicare payments and services.

474.56 Reinstatement after exclusion.

Subpart G—Appeals

474.58 Appeal rights.

Authority: Section 1102 of the Social Security Act, 42 U.S.C. 1302. Subpart B is also issued under sec. 150 of Pub. L. 97-248, 42 U.S.C. 1320c note. Subparts C through G are also issued under sec. 1156 of the Social Security Act, 42 U.S.C. 1320c-5.

2. A new Subpart A entitled "General Provisions" is established to include the current § 474.0.

3. Section 474.0 is revised to read as follows:

§ 474.0 Scope and definitions.

(a) *Scope.*

This part implements section 150 of Pub. L. 97-248 (PSROs) and section 1156 of the Act (PROs) by—

(1) Setting forth certain obligations imposed on practitioners and providers of services under Medicare;

(2) Establishing criteria and procedures for the reports required from PSROs and PROs when there is failure to meet those obligations;

(3) Specifying the policies and procedures for making determinations on violations and imposing sanctions; and

(4) Defining the procedures for appeals by the affected party and the procedures for reinstatements.

(b) *Definitions.* As used in this part, unless the context indicates otherwise:

"Economically" means that services are provided at the least expensive, medically appropriate type of setting or level of care available.

"Exclusion" means that items or services furnished or ordered by a specified health care practitioner, provider, or other person during a

specified period are not reimbursed under Medicare.

"Gross and flagrant violation" means a violation of an obligation has occurred in one or more instances which presents an imminent danger to the health, safety or well-being of a Medicare beneficiary or places the beneficiary unnecessarily in high-risk situations.

"Health care services" or "Services" means services or items for which payment may be made (in whole or in part) under the Medicare program.

"Obligation" means any of the obligations specified at section 1156(a) of the Act.

"OIG" stands for the Office of the Inspector General, Department of Health and Human Services.

"Other person" means a hospital or other health care facility, an organization, or an agency that furnishes health care services for which payment may be made under the Medicare program.

"Physician" means a doctor of medicine or osteopathy or another individual who is authorized under State or Federal law to practice medicine and surgery or osteopathy.

"Practitioner" means a physician or other health care professional licensed under State law to practice his or her profession.

"PRO area" means the geographic area subject to review by a particular PRO.

"Provider" means a hospital or other health care facility, agency, or organization.

"PSRO area" means the geographic area subject to review by a particular PSRO.

"Sanction" means an exclusion or monetary penalty that the Secretary may impose on a practitioner or other person as a result of a recommendation from a PRO.

"Substantial violation in a substantial number of cases" means a pattern of care has been provided that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the PRO.

4. A new Subpart B entitled "Sanctions Under the PSRO Program" is established to include current §§ 474.1-474.17.

5. New Subparts C through G are added to read as follows:

Subpart C—Sanctions Under the PRO Program: General Provisions**§ 474.30 Statutory obligations of practitioners and other persons.**

It is the obligation of any health care practitioner or other person who furnishes or orders health care services that may be reimbursed under Medicare, to ensure, to the extent of his or her authority, that those services are—

(a) Furnished economically and only when and to the extent medically necessary;

(b) Of a quality that meets professionally recognized standards of health care; and

(c) Supported by evidence of the medical necessity and quality of the services in the form and fashion that the reviewing PRO may reasonably require (including copies of the necessary documentation and evidence of compliance with pre-admission or pre-procedure review requirements to ensure that the practitioner or other person is meeting the obligations imposed by section 1156(a) of the Act.

§ 474.32 Sanctions.

In addition to any other sanction provided under law, a practitioner or other person may be—

(a) Excluded from Medicare; or

(b) In lieu of exclusion and as a condition for continued participation in Medicare, if the violation involved the provision or ordering of health care services that were medically improper or unnecessary, required to pay an amount not in excess of the cost of the improper or unnecessary services that were furnished or ordered. The practitioner or other person will be required either to pay the monetary assessment within 6 months of the date of notice or have it deducted from any sums the Federal Government owes the practitioner or other person.

Subpart D—PRO Responsibilities**§ 474.34 Basic responsibilities.**

(a) The PRO must use its authority or influence to enlist the support of other professional or government agencies to ensure that each practitioner or other person complies with the obligations specified in § 474.30.

(b) The PRO must identify situations where the obligations specified in § 474.30 are violated and afford the practitioner or other person reasonable notice and opportunity for discussion in accordance with §§ 474.36 and 474.38.

(c) The PRO must submit a report to the OIG after the notice and opportunity provided under paragraph (b) of this

section, if the PRO determines that the practitioner or other person has—

(1) Failed substantially to comply with any obligation in a substantial number of cases; or

(2) Grossly and flagrantly violated any obligation in one or more instances.

(d) The PRO report to the OIG must comply with the provisions of § 474.40.

(e) The PRO must deny services or items ordered by an excluded practitioner or other person when the PRO identifies the services or items and reports the findings to HCFA.

§ 474.36 Action on identification of a violation.

When a PRO identifies a violation, it must determine the nature of the violation.

(a) If the PRO determines the violation as one that is gross and flagrant, it must proceed in accordance with § 474.38.

(b) If the PRO determines the violation as a substantial violation in a substantial number of cases it must send the practitioner or other person a written initial notice of the identification of a violation containing the following information:

(1) The obligation involved.

(2) The situation, circumstances, or activity that resulted in a violation.

(3) The authority and responsibility of the PRO to report violations of obligations.

(4) At the discretion of the PRO, a suggested method for correcting the situation and a time period for corrective action.

(5) The sanction that the PRO could recommend to the OIG if the violation continues.

(6) An invitation to submit additional information to or discuss the problem with representatives of the PRO within 20 days of receipt of the notice. The date of receipt is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(7) A summary of the information used by the PRO in arriving at its determination of a violation of an obligation.

§ 474.38 Action on determination of a violation.

(a) *Written notice.* The PRO must give written notice to the practitioner or other person if it determines that—

(1) A substantial violation has occurred in a substantial number of cases; or

(2) A violation is gross and flagrant in one or more cases.

(b) *Contents.* The notice must contain the following information:

(1) The determination of a violation.

(2) The obligation violated.

(3) The basis for the determination.

(4) The sanction the PRO will recommend to the OIG.

(5) The right of the practitioner or other person to submit to the PRO within 30 days of receipt of the notice, additional information or a written request for a meeting with the PRO to review and discuss the determination, or both. The date of receipt is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(6) A copy of the material used by the PRO in arriving at its determination.

(c) *Review of PRO determination.*

(1) The PRO may, on the basis of additional information received, affirm, modify, or reverse its determination.

(2) The PRO must give written notice to the practitioner or other person, of any action it takes as a result of the additional information received, as specified in § 474.39.

§ 474.39 Final PRO determination of a violation.

If the issue is not resolved to the PRO's satisfaction as specified in § 474.38(c), the PRO must—

(a) Submit its report and recommendation to the OIG; and

(b) Send the affected practitioner or other person a concurrent final notice, with a copy of the PRO report that is being forwarded to the OIG, advising that—

(1) The PRO recommendation has been submitted to the OIG;

(2) The practitioner or other person has 30 days from receipt of this final notice to submit any additional material to the OIG at its central office location. The date of receipt is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary; and

(3) Due to the 120-day statutory requirement specified at § 474.42(e), the period for submitting additional information will not be extended and any material received by the OIG after the 30-day period will not be considered.

§ 474.40 PRO report to OIG.

(a) *Manner of reporting.* If the PRO determines that a substantial violation has occurred in a substantial number of cases or that a gross and flagrant violation has occurred, it must submit a report and recommendation to the OIG at the regional office with jurisdiction.

(b) *Content of report.* The PRO report must include the following information—

(1) Identification of the practitioner or other persons and when applicable, the

name of the director, administrator, or owner of the entity involved;

(2) The type of health care services involved;

(3) A description of each failure to comply with an obligation, including specific dates, places, circumstances, and any other relevant facts;

(4) Pertinent documentary evidence;

(5) Copies of written correspondence and written summaries of oral exchanges with the practitioner or other person regarding the violation;

(6) The PRO's determination that an obligation under section 1156(a) of the Act has been violated and that the violation is substantial and has occurred in a substantial number of cases or is gross and flagrant;

(7) The professional qualifications of the PRO's reviewers; and

(8) The PRO's sanction recommendation.

(c) *PRO Recommendation.* The PRO must specify in its report—

(1) The sanction recommended;

(2) The amount of the monetary penalty recommended, if applicable;

(3) The period of exclusion recommended, if applicable; and

(4) A recommendation as to whether the practitioner or other person is unable or unwilling substantially to comply with the obligation that was violated.

§ 474.41 Basis for recommended sanction.

The PRO's specific recommendation must be based on a consideration of—

(a) The type of offense involved;

(b) The severity of the offense;

(c) The deterrent value;

(d) The practitioners' or other person's previous sanction record;

(e) The availability of alternative sources of services in the community; and

(f) Any other factors that the PRO considers relevant (for example, the duration of the problem).

Subpart E—OIG Responsibilities

§ 474.42 Acknowledgement and review of report.

(a) *Acknowledgement.* The OIG will inform the PRO of the date it received the PRO's report and recommendation.

(b) *Review.* The OIG will review the PRO report and recommendation to determine whether—

(1) The PRO is following its procedures;

(2) A violation has occurred; and

(3) The practitioner or other person has demonstrated an unwillingness or lack of ability substantially to comply with an obligation.

(c) *Rejection of the PRO recommendation.* If the OIG decides

that a sanction is not warranted, it will notify the PRO that recommended the sanction and the affected practitioner or other person that the recommendation is rejected.

(d) *Decision of sanction.* If the OIG decides that a violation of obligations has occurred, it will determine the appropriate sanction by considering—

(1) The recommendation of the PRO;

(2) The type of offense;

(3) The severity of the offense;

(4) The previous sanction record of the practitioner or other person;

(5) The availability of alternative sources of services in the community;

(6) Any prior problems the Medicare carrier or intermediary has had with the practitioner or other person;

(7) Whether the practitioner or other person is unable or unwilling to comply substantially with the obligations; and

(8) Any other matters relevant to the particular case.

(e) *Exclusion sanction.* If the PRO submits a recommendation for exclusion to the OIG, and a determination is not made by the 120th day after actual receipt by the OIG, the exclusion sanction recommended will become effective and the OIG will provide notice in accordance with § 474.52(f).

(f) *Monetary penalty.* If the PRO recommendation is to assess a monetary penalty, the 120-day provision does not apply and the OIG will provide notice in accordance with § 474.52 (a) through (e).

§ 474.52 Notice of sanction.

(a) The OIG notifies the practitioner or other person of the adverse determination and of the sanction to be imposed.

(b) The sanction is effective 15 days from the date of receipt of the notice. The date of receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary.

(c) The notice specifies—

(1) The legal and factual basis for the determination;

(2) The sanction to be imposed;

(3) The effective date and, if appropriate, the duration of the exclusion;

(4) The appeal rights of the practitioner or other person; and

(5) In the case of exclusion, the earliest date on which the OIG will accept a request for reinstatement.

(d) The OIG notifies the public by publishing in a newspaper of general circulation in the PRO area a notice that identifies the sanctioned practitioner or other person, the obligation that has been violated, the sanction imposed and, if the sanction is exclusion, the effective date and duration.

(e) Notice of the sanction is also provided to the following entities as appropriate:

(1) The PRO that originated the sanction report.

(2) PROs in adjacent areas.

(3) State Medicaid fraud control units and State licensing bodies.

(4) Appropriate Medicare contractors and State agencies.

(5) Hospitals, including the hospital where the sanctioned individual's case originated and where the individual currently has privileges, if known; skilled nursing facilities, home health agencies, and health maintenance organizations (HMOs).

(6) Medical societies and other professional organizations.

(7) Medicare carriers and intermediaries, health care prepayment plans, and other affected agencies and organizations.

(f) If an exclusion sanction is effected because a decision was not made within 120 days after receipt of the PRO recommendation, notification is as follows:

(1) The OIG notifies the practitioner or other person that the exclusion from the Medicare program is effective 15 days from the date the notice is received by the practitioner or other person. The date of receipt is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(2) Notice of the sanction is also provided as specified in paragraph (e) of this section.

(3) As soon as possible after the 120th day, the OIG will issue a notice to the practitioner or other person affirming the PRO recommendation or modifying the recommendation based on the OIG's review of the case.

(g) The determination and notice of sanction provided for in this section constitute an "initial determination" and a "notice of initial determination" for purposes of the administrative appeals procedures specified in Part 405, Subpart O of this chapter concerning determinations and appeals procedures for providers and suppliers.

Subpart F—Effect and Duration of Exclusion

§ 474.54 Effect of an exclusion on Medicare payments and services.

(a) *General provisions.* Except as provided under paragraphs (b) and (c) of this section—

(1) Payment will not be made under Medicare to an excluded practitioner or other person for services or items furnished or ordered during the period of exclusion;

(2) Payment will not be made under Medicare to any provider for services or items ordered by an excluded practitioner or other person when the order was a necessary precondition for payment under Medicare; and

(3) Assignment of a beneficiary's claim for services or items furnished or ordered by an excluded practitioner or other person on or after the effective date of exclusion will not be valid.

(b) *Exceptions.* Payment is available for services or items provided up to 30 days after the effective date of an exclusion for—

(1) Inpatient hospital or skilled nursing services or items furnished to a beneficiary who was admitted before the effective date of the exclusion; and

(2) Home health services or items furnished under a plan established before the effective date of the exclusion.

(c) *Denial of payments to beneficiaries.* If a beneficiary submits claims for services or items furnished or ordered by an excluded practitioner or other person on or after the effective date of exclusion—

(1) HCFA pays the first claim submitted and immediately gives the beneficiary notice of the exclusion; and

(2) The beneficiary's right to payment extends to services or items furnished or ordered up to 15 days after the date on the notice.

(d) *Effective date of termination of provider agreement.* The effective date of termination of a Medicare provider agreement is determined in accordance with §§ 489.53 and 489.55 of this chapter.

§ 474.56 Reinstatement after exclusion.

Exclusion will remain in effect until—

(a) The OIG determines, in accordance with §§ 420.130 through 420.136 of this chapter, that the basis for the exclusion no longer exists and there is reasonable assurance that the problems will not recur; or

(b) The OIG's determination to exclude is reversed by a hearing decision.

Subpart G—Appeals

§ 474.58 Appeal rights.

(a) *Right to administrative review.*

(1) A practitioner or other person dissatisfied with an OIG determination or an exclusion that results from a determination not being made within 120 days is entitled to a hearing before

an Administrative Law Judge and may also request a review of that decision by the Appeals Council in accordance with §§ 405.1530 through 405.1595 of this chapter.

(2) Due to the 120-day statutory requirement specified at § 474.42(e) of this part, the following limitations apply:

(i) The period for submitting additional information will be not be extended.

(ii) Any material received by the OIG after the 30-day period allowed, will not be considered and will not be subject to review by the Administrative Law Judge and the Appeals Council.

(3) OIG's determination continues in effect unless reversed by a hearing decision.

(b) *Right to judicial review.* Any practitioner or other person dissatisfied with a decision of the Appeals Council or an administrative law judge (if a request for Appeals Council review is denied), may file a civil action in accordance with the provisions of section 205(g) of the Act.

PART 489—PROVIDER AGREEMENTS UNDER MEDICARE

D. Part 489 is amended as follows:

1. The authority citation for Part 489 continues to read as follows:

Authority: Secs. 1102, 1861, 1864, 1866, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395aa, 1395cc, and 1395hh).

2. Section 489.55 is revised to read as follows:

§ 489.55 Exceptions to effective date of termination.

Payment is available for up to 30 days after the effective date of termination for—

(a) Inpatient hospital services (including inpatient psychiatric hospital services) and posthospital extended care services furnished to a beneficiary who was admitted before the effective date of termination; and

(b) Home health services furnished under a plan established before the effective date of termination.¹

(Catalog of Federal Domestic Assistance Programs, No. 13.773, Medicare—Hospital Insurance and No. 13.774, Medicare—Supplementary Medical Insurance)

¹ For terminations before July 18, 1984, payment was available through the calendar year in which the termination was effective.

Dated: December 11, 1984.

Carolyn K. Davis,

Administrator, Health Care Financing Administration.

R.P. Kusserow,

Inspector General, Department of Health and Human Services.

Approved: January 28, 1985.

Margaret M. Heckler,

Secretary.

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42 CFR Parts 400 and 476

[HSQ-110-F]

Medicare Program; Acquisition, Protection, and Disclosure of Utilization and Quality Control Peer Review Organization (PRO) Information

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: These regulations govern the acquisition, protection, and disclosure of information obtained or generated by Utilization and Quality Control Peer Review Organization (PROs). The Peer Review Improvement Act of 1982 authorizes PROs to acquire information necessary to fulfill their duties and functions, places limits on disclosure of PRO information, and establishes penalties for unauthorized disclosure. These regulations implement the PROs' statutory right of access to necessary information and set forth their responsibilities to assure that information once acquired is adequately safeguarded and disclosed only for proper purposes.

EFFECTIVE DATE: The regulations are effective May 17, 1985.

Sections 476.105, 476.116, and 476.134 of this rule contain information collection requirements with which the public is not required to comply until the Executive Office of Management and Budget (EOMB) approves these requirements. (See section VI. of the preamble for a discussion of information collection.)

FOR FURTHER INFORMATION CONTACT:

Mary K. Terry, (301) 594-7910.

SUPPLEMENTARY INFORMATION:

I. Legislative History

The Peer Review Improvement Act of 1982 (Title I, Subtitle C of the Tax Equity and Fiscal Responsibility Act of 1982 (Pub. L. 97-248)) amended Part B of Title XI of the Social Security Act (Act) to establish the Utilization and Quality

Control Peer Review Organization (PRO) program.

Congress originally enacted Part B of Title XI in 1972, establishing the Professional Standards Review Organization (PSRO) program. The purpose of the PSRO program was to assure that health care services and items for which payment may be made under the Medicare, Medicaid and Maternal and Child Health and Crippled Children's programs were medically necessary, conformed to appropriate professional standards and were delivered in the most efficient and economical manner possible. The 1982 legislation provided for PROs to assume PSRO responsibilities for the review of health care services funded under Title XVIII of the Act (Medicare) to determine whether those services are medically necessary, are furnished at the appropriate level of care, and are of a quality that meets professionally recognized standards. In addition, PROs will monitor and validate a sample of diagnostic and procedural information supplied by providers to fiscal intermediaries regarding prospective payments to hospitals. To carry out their responsibilities PROs, like PSROs, will acquire information from the medical records of patients and from other records maintained by health institutions, practitioners, and claims payment agencies. In addition, they will generate information regarding the quality and appropriateness of health care services. PROs will use this information to develop and review profiles (patterns of utilization and practice) and to assess the quality of care being furnished. PROs will then transmit their determinations to organizations responsible for making payments under the Act.

The PRO legislation contains several provisions affecting data collection and disclosure. Under section 1154(a)(7)(C) of the Act, PROs have the authority to examine pertinent records of any practitioner or provider of health care services for which the PRO has review responsibility. Section 1154(a)(9) of the Act requires that PROs "collect such information relevant to its functions, and keep and maintain such records, in such form as the Secretary may require to carry out the purposes of this part, and shall permit access to and use of any such information and records as the Secretary may require for such purposes, subject to the provisions of section 1160." The other relevant language in section 1154 authorizes PROs to exchange information with claims payment agencies, other PROs and other public or private review

organizations as may be appropriate (section 1154(a)(10)). Section 1160 of the Act contains the majority of a PRO's statutory responsibilities concerning the disclosure of information. This section recognizes both the need to protect the interests of patients, health care practitioners and providers of health care in the confidentiality of their medical records and the need to disclose certain information.

II. Proposed Rule

On April 16, 1984 we published in the Federal Register a proposed rule that would implement that part of the PRO statute concerning acquisition, protection, and disclosure of PRO information (49 FR 14977). The major provisions of the proposed rule are as follows:

A. General Provisions

1. PRO information must be held in confidence and not be disclosed unless the disclosure is necessary to carry out the purposes of the PRO statute or is provided for by regulations published by the Secretary.

2. The proposal describes the procedures for disclosure by a PRO of information necessary to carry out the purposes of the statute, including notice requirements, limitations on redisclosure and penalties for unauthorized disclosure. It also specifies the applicability of certain other statutes and implementing regulations to PRO information.

B. PRO Access to Information

1. Under the proposal, PROs are permitted to require institutions or practitioners to provide to the PRO copies of records and information pertinent to health care services furnished in the PRO area to Medicare beneficiaries. If authorized by the institution of practitioner, PROs also have access to the records of other patients.

2. PROs are permitted to have access to records held by Medicare intermediaries or carriers and certain other information collected or generated by institutions, practitioners or other entities. Certain limitations on PRO data collection were also specified in the proposed regulations.

C. PRO Responsibilities

1. In the proposal, we delineate PRO responsibility for: maintaining the confidentiality of information in their possession, including the responsibilities of PRO officers and employees; training requirements, including those for persons with authorized access to confidential information; purging of

personal identifiers; and data systems procedures.

2. A PRO would be required to place a public notice in a newspaper announcing the existence of its data system, the types of information acquired by the PRO, and the procedures by which each patient, practitioner, and institution may obtain information about themselves.

D. Disclosure of Nonconfidential Information

Disclosure of nonconfidential information would be required of PROs regardless of the source of the request. PROs may also disclose this information to anyone who they believe would be interested in the information.

E. Disclosure of Confidential Information

1. The proposal requires the disclosure of all information requested by the Department. The Department includes HCFA and other Departmental components that are responsible for assuring that funds for the PRO programs are expended in accordance with the law and regulations.

2. The April 16th document permits some disclosure of patient-identified information to a patient or his or her representative. If the patient's request is not made in connection with a denial decision, the proposed regulations require the PRO to allow the attending practitioner an opportunity to comment on the appropriateness of disclosing the information to the patient.

3. Under the proposed rule, disclosure of practitioner-identified information is permitted only to the individual practitioner, to the institution where the individual practices or, with the practitioner's consent, to any designated person, agency or organization.

4. PROs would be required to provide limited access to certain identifying information to Federal and State agencies, including fraud and abuse agencies and licensing and certification bodies and researchers, who have a significant need for information to carry out their recognized responsibilities or in order to avoid duplication in collecting and processing information. PRO information must be disclosed to public health agencies if the PRO determines the disclosure of the information is necessary to protect against and imminent danger to individuals or to the public health.

5. PRO deliberations must not be disclosed except to HCFA or the Office of the Inspector General (OIG). The reasons for PRO decisions may be disclosed.

6. The proposal would require disclosure of quality review studies with identifiers, but only on-site and only to: practitioners or institutions identified in the study; authorized personnel from the General Accounting Office; HCFA; accreditation, licensure, and certification bodies; Federal and State fraud and abuse agencies; and, under certain circumstances, a medical review board established under section 1881 of the Act which pertains to End Stage Renal Disease facilities.

7. PROs could disclose their interpretations of the quality of health care in a particular institution to the public.

8. PROs would be required to disclose sanction reports directly to the OIG, HCFA, and Federal and State fraud and abuse agencies.

9. In addition to PRO's authorization to disclose information at their discretion to carry out the purposes of the PRO statute, the proposal gives PROs discretion to disclose confidential information to research agencies and establishes criteria and guidelines for the PRO to use in exercising this discretion.

III. Public Comments

We received over 160 letters of comment in response to the proposed rule. Comments were received from hospitals, State and national medical associations, hospital councils, peer review organizations, members of Congress and other interested parties. The comments and our responses to those comments are set forth below:

A. General Provisions

1. Definition of confidential information.

Comment: One commenter stated that the definition of confidential information in § 476.101(b) of the proposed rule was inconsistent with the statute in the section 1160(b)(2) of the Act recognizes as confidential only statistical data that explicitly identify an individual. Therefore, data that implicitly identify an individual would be considered non-confidential.

Response: The PRO statute does not support such a distinction between explicit and implicit disclosure. We believe that permitting the disclosure of information that identifies an individual, even though not explicitly, would undermine the rationale of the statute. The statute does not preclude our prohibiting the disclosure of such information, and the intent of the statute is to limit the disclosure of information concerning identifiable individuals to specific situations, whether that identification is implicit or explicit.

2. Distinction between confidential and non-confidential information.

Comment: We received several comments regarding the distinction between confidential and non-confidential information. Some thought that the regulations should adhere more closely to the statutory presumption that all PRO data should be held in confidence except under clearly defined circumstances.

Response: We are retaining the distinction between confidential and non-confidential information in order to permit the disclosure of information that does not identify an individual and to limit the release of patient- or practitioner-identified information to that required for PRO review or for other statutorily mandated reasons. Section 1160(a)(2) of the Act imposes on the Secretary the statutory obligation to identify in regulations the cases and circumstances under which PRO information may be disclosed.

3. Notice requirements—15 days.

Comment: Fifteen commenters believed that § 476.105 of the regulations should require PROs to give more than 15 calendar days notification to institutions before the disclosure of information about the institution that is not routinely prepared for PRO use.

Response: We agree and are changing the 15 calendar day notification requirement in § 476.105 to 30 calendar days. In addition, if the comments are received after the 30-day timeframe, the PRO is obligated to forward the comments to the recipient of the disclosed information.

We are revising § 476.105(a) to clarify that the PRO must notify an identified institution of the PRO's intention to disclose information, other than reports routinely submitted to HCFA (including Medicare fiscal agents) or reports submitted to or from PRO subcontractors or to or from an institution, about that institution.

4. Exceptions to PRO notice requirements.

Comment: Several commenters disagree with the exception to the notice requirements (§ 476.106) that PROs need not notify an institution of a disclosure if the disclosure is made in an investigation of fraud or abuse and the information is related to a potentially prosecutable offense. The commenters believe that practitioners and providers should be notified by the PRO when fraud or abuse is suspected in a potentially prosecutable offense.

Response: We understand the commenters concern; however, any such notification would serve only to impede the investigation of fraud or abuse. We believe this exception is required to

protect the investigative process in pursuing cases involving fraud or abuse. We are modifying § 476.106 to require that all investigative agencies except the Office of the Inspector General and General Accounting Office (GAO), must specify in writing to the PRO that the information requested is related to a potentially prosecutable criminal offense.

5. Limitations on redisclosure.

Comment: One commenter requested that we clarify § 476.107, Limitations on redisclosure, to prevent the release of information that identifies individuals other than the individual who is releasing the information.

Response: This section permits a patient or practitioner to redisclose information about himself or herself and permits an institution to redisclose information about itself. We agree with the commenter that there is a potential in the section, as written, for information to be released that might identify other individuals. Therefore, we are modifying § 476.107(g) to state that information pertaining to a patient or practitioner may be redisclosed by those individuals provided it does not identify any other patient or practitioner.

Comment: One commenter requested that we modify § 476.107(h) to restrict redisclosure by an institution if the redisclosure would identify a practitioner.

Response: We believe this is a valid concern; therefore, we have modified § 476.107(h) to state that an institution may disclose information pertaining to itself provided the information does not identify an individual practitioner or patient.

Comment: Several commenters stated that the regulation does not adequately address the redisclosure of confidential information by public agencies.

Response: We believe we have sufficiently limited redisclosure by public agencies under § 476.107 (i) and (j) of the regulations. These paragraphs specify the instances when public agencies can redisclose information, such as in a judicial, administrative or other formal legal proceeding resulting from an investigation conducted by the agency receiving the information. We also believe there is an overwhelming need to ensure that State and local public health officials are able to redisclose appropriate information where there is substantial risk to the public health. Therefore, we are permitting additional redisclosures by public health agencies in order to protect the interests of patients, practitioners and providers under section 1160(a)(2) of the Act. In addition,

we have modified paragraph (f) for clarification and are adding a paragraph (k) to permit redisclosure as necessary for the OIG and GAO to carry out their statutory responsibilities.

We do not believe any further changes are necessary to regulations. However, to be consistent with the statute we have deleted from § 476.107(i) the reference to Federal and State health planning agencies. Also, Federal and State health planning agencies do not receive confidential information under the PRO statute; therefore, they are not subject to the redisclosure limitations contained in § 476.107.

6. Penalties for unauthorized disclosure.

Comment: Several commenters believed that the penalties for unauthorized disclosure should be strengthened.

Response: Section 1160(c) of the statute provides for the penalties described in § 476.108 of the regulations; therefore, we are making no change to the regulations based on this comment. However, we are correcting a grammatical error in the second half of the sentence in § 476.108 to now read: "... be fined no more than \$1000 or imprisoned for no more than 6 months, or both ..." (emphasis added).

7. Extent of an institution's right to privacy.

Comment: Seventy-five commenters stated that because §§ 476.120(g) and 476.141 allow for disclosure of information that identifies a particular institution, there is a potential for misinterpretation and misuse of these data with no due process for institutions.

Response: Section 476.120(g) (redesignated as § 476.120(a)(7)) provides for disclosure of nonconfidential aggregate statistical information that does not identify individual patients, practitioners or reviewers and § 476.141 provides for the disclosure of PRO interpretations, and generalizations on the quality of care that identify a particular institution. We agree with the commenters and have made several changes to the regulations based on the ideas contained in those comments. The following changes will afford a provider the protection needed to avoid possible misinterpretation where the PRO releases data concerning that provider. We have specified that §§ 476.120(a)(7) and 476.141 are subject to the procedures for disclosure and notice of disclosure specified in §§ 476.104 and 476.105 that require a PRO to notify an institution of its intent to disclose information about the institution that is not routinely prepared for PRO use, provide the institution with

a copy of that information, and give the institution an opportunity to comment on the information. Further, as stated earlier in the comment on the 15-day notice requirement, we have amended that requirement to extend the time period for a provider to comment on disclosed information from 15 to 30 calendar days, thereby providing additional protection for hospitals.

We therefore believe that the final rule assures adequate protection of the rights and interests of institutions, because under these regulations the institution has the opportunity to provide explanatory statements regarding the data which the PRO is considering disclosing. For example, if the PRO's statistics relate to mortality, the hospital might include additional information such as case mix statistics, the severity of the illnesses treated, or the number and ages of its patients. If the PRO releases nosocomial infection rate data, the hospital could add information regarding special services susceptible to such infections, such as burn units. The PRO must attach these comments to the disclosed material. However, to alleviate some confusion, we have also revised the phrase "not routinely prepared for PRO use" to make reference instead to reports routinely submitted to HCFA (including Medicare fiscal agents) or reports submitted to or from PRO subcontractors or to or from an institution.

Comment: One commenter requested that we define the phrase "interpretations and generalizations on the quality of health care" as used in § 476.141.

Response: A PRO's "interpretations and generalizations on the quality of health care" means an assessment of the quality of care furnished by an individual provider or group of providers based on the PRO's knowledge of the area gained from its medical review experience (e.g., quality review studies) and any other information obtained through the PRO's review activities.

Comment: Thirty-nine commenters objected to the exclusion of information that identifies hospitals from the proposed definition of confidential information.

They believe that hospitals should be afforded the same protection as practitioners in terms of disclosure policies.

Response: Section 1160(a)(2) of the Act states that the Secretary shall provide by regulation for adequate protection of the interests of patients as well as for practitioners and providers. Public interest is served by providing access to certain PRO data by the public or by agencies that have public

responsibilities to which PRO data are relevant. PROs deal with matters of great public concern—the provision and cost of health care.

They are, therefore, an important source of information to aid consumers and consumer organizations in reaching informed decisions about the types of health care services that are offered. Also, the policy of disclosure of provider-specific, but not practitioner-specific information is supported by recommendations in the congressionally mandated Institute of Medicine October 1981 study entitled "Access to Medical Review Data: Disclosure Policy For Professional Standards Review Organizations".

However, while we believe that disclosing provider information is appropriate and necessary to the public interest, we do not intend that such disclosure be misused. As stated in the previous comment, the regulations contain the requirement that the institution may submit comments on information to be disclosed and the PRO must attach these comments to the disclosed material. Also, the regulations contain the caveat that a PRO must not release nonconfidential information in instances where the identity of a patient, practitioner or reviewer, e.g., publishing the surgical mortality rates of a hospital that has only one surgeon, will be obvious to an individual with an understanding of the area.

B. PRO Access to Information

1. Access to information from institutions and practitioners

Comment: Section 476.111(b) of the proposed rule permits PROs to have access to and obtain information from records of non-Medicare patients, if access is authorized by the institution or practitioner. Fifty-two commenters believed that this section is ambiguous regarding PRO access to records of private-pay patients, and that the patient's consent should be required before a PRO is given access.

Response: We agree. We are adding a new § 476.111(b) to clarify that PROs may obtain specific non-Medicare patient records relating to review the PRO performs under non-Medicare contracts if authorized by those patients in accordance with State law. We are redesignating the proposed paragraph § 476.111(b) as paragraph (c) and modifying it to specify that PROs may have access to and obtain records of non-Medicare patients who are not covered under a private review contract held by the PRO only in connection with their quality review responsibilities and

only if authorized by the institution or practitioner.

Quality review is an integral and essential element of the PRO statute. Section 1154(a)(1)(B) of the Act specifies that any PRO must (in accordance with its contract with the Secretary) perform review to determine whether the quality of care provided to Medicare beneficiaries meets professionally recognized standards of health care. Furthermore, this PRO requirement represents the continuation of a peer review function mandated by Medicare statute over the past ten years. Also, in section 1154(a)(8), the Congress provides the same process for PROs as it had for earlier Medicare peer review for prescribing the way in which quality review would be performed by PROs, namely, regulations of the Secretary. The provisions of section 1154(a)(7)(D) and (a)(9) direct PROs, in a way similar to earlier peer review organizations, to inspect facilities and collect information necessary to carry out PRO review functions, including quality review. Section 1866(a)(1)(E) imposes a similar obligation on Medicare providers to release patient care data to PROs for review purposes including the conduct of Medicare quality review.

Taken together, these provisions give statutory authority to PROs to conduct quality review in the same manner as conducted by previous Medicare peer review organizations.

The quality review process consists of screening patient care information to identify and verify quality problems in addition to conducting quality review studies. A quality review study (QRS) is an assessment conducted by or for a PRO of a patient care problem for the purpose of improving the patient care of some of all providers or practitioners in the PRO area through peer analysis, intervention, and resolution of the problem and follow-up. Patient consent is not needed to access these records because unlike utilization review under private contracts, PRO quality review assesses the professional practice patterns of providers and practitioners.

While the identified problem must affect Medicare patients, it usually affects other patients as well, especially in the context of acute inpatient care. This is because quality problems relate to the way in which care is delivered (i.e., the behavior of a provider or practitioner). In some of these cases, a problem can be adequately addressed for Medicare patients only by addressing the problem for all patients in an acute care setting.

This means that in some quality review studies a PRO must review both Medicare and non-Medicare patient

records in order to resolve the problem for Medicare patients. For example, a Medicare quality review study may seek to analyze and resolve a problem concerning the increase in the rate of post-operative infections in certain operations when prophylactic antibiotics were not used. However, for individual providers or specific practitioners, the frequency with which certain operations are performed on Medicare patients may be too low to draw reliable conclusions about the proper use of these antibiotics by that practitioner or in that provider on a timely basis (i.e., it may take a year of data collection for Medicare patients only). In contrast, the frequency with which these operations are performed on all patients may be adequate to permit timely and reliable assessment of the problem (i.e., within one to three months) and permit more rapid problem resolution for Medicare patients.

Also, physician and hospital-wide studies encourage general resolution of problems through the alteration of area practice patterns. This benefits both Medicare and non-Medicare patients and assures more substantive and longer lasting improvement in a problem than could have been achieved by focusing only on Medicare patients.

2. Access to information of intermediaries and carriers.

Comment: We received comments on various aspects of the provision set forth in § 476.112. Several commenters believed the regulation is vague as to what records and information (private or Medicare records) are available to the PRO. Several commenters requested that we add time periods for the transfer of information to the PRO. One commenter believed that the protection of confidential information transmitted by fiscal agents to PROs is not safeguarded through any clearly stated mechanism. Two commenters recommended patient consent before PROs could obtain access to patient records and information held by intermediaries or carriers. Regarding patient consent, one commenter believed that subsequent PRO disclosures of data could go beyond the intent of the individual who authorized the fiscal agent to obtain the data originally.

Response: We agree with commenters concerning the vagueness as to what records and information are available to the PRO under this provision. We are, therefore, modifying § 476.112 to specify that PROs can access only Medicare records or information held by intermediaries or carriers.

We do not believe it is necessary to specify in regulations time periods and

safeguards for the transfer of information to the PRO because they will be covered in each PRO's agreement with a fiscal agent. The requirements for maintaining the confidentiality of information transferred to PROs are covered under § 476.115. Therefore, it is not necessary to add any additional safeguards in § 476.112.

Concerning the comments on patient consent, we do not believe it is necessary to obtain separate patient consent prior to accessing each record or piece of information, because patient consent is already given as a condition of payment under Medicare. For subsequent PRO disclosures that might go beyond the original intent of the authorizing individual, we believe the disclosure and redisclosure provisions contained in these regulations are sufficiently detailed and comprehensive to adequately protect the rights of individual patients. We are, therefore, making no changes to the regulations with regard to this issue.

3. Access to information collected for PRO purposes.

Comment: Several commenters believed that the provisions under § 476.113 requiring institutions to disclose to a PRO information collected for PRO purposes and information generated in quality review studies would allow a PRO access to internal hospital review and quality assurance decisions rather than only that information needed for a PRO's QRS.

Response: We agree that there is potential for PROs to have access to internal hospital review documents and do not believe it is proper to allow PROs such broad access to hospital records. Therefore, we are changing the definition of "quality review study" in § 476.101 to clarify that a QRS for purposes of these regulations means only a QRS conducted by or for a PRO. Thus, a PRO would not have access to a hospital's quality assurance information not collected for a PRO. We are also modifying this definition to conform to the definition of "quality review study" contained in § 466.1 of final regulations concerning a PRO's assumption of review published elsewhere in this issue of the Federal Register.

4. Limitation on data collection.

Comment: Two commenters thought that proposed § 476.114 should be expanded to include private patient data as well.

Response: The statutory bases for § 476.114, which are contained in sections 1154 (a)(7)(C) and (a)(9) of the Act, provide a PRO with access to information for the purposes of carrying

out its responsibilities under Title XI of the Act which, under circumstances described in § 476.111 may include non-Medicare patient information.

However, we are clarifying in § 476.114 that the reference to 44 U.S.C., Chapter 35 refers only to the PRO's collection of information as a Federal contractor.

C. PRO Responsibilities

1. Requirements for maintaining confidentiality.

Comment: The proposed § 476.115(d)(1) permits authorized access to confidential PRO information to an individual who "is undergoing or has completed a training program" in the proper handling of PRO information. We received two comments requesting that we delete the phrase "is undergoing".

Response: We agree with these commenters and are amending § 476.115(d) as requested. The training required to assure appropriate handling of confidential peer review data is generally accomplished within a short period. Therefore, it does not appear that requiring this training to be completed prior to permitting an individual to have access to this information would unduly burden a PRO.

Comment: One commenter suggested that training in the handling of confidential information should be a condition of PRO employment.

Response: We believe that the handling of confidential information is important. Therefore, § 476.115(c) requires that a PRO train participants of the PRO review system in the proper handling of confidential information, and § 476.115(d), as amended under these final regulations, does not permit an individual participating in the PRO review system on a routine or ongoing basis to have authorized access to confidential PRO information until that individual has completed a training program in the handling of PRO information. We believe that these provisions provide the necessary safeguards for the handling of confidential information without unduly restricting the PRO's abilities to hire staff.

Comment: One commenter believed that under § 476.115(e)(1) of the regulations PROs should be able to determine when it is appropriate to purge personal identifiers from PRO files rather than requiring them to wait for notification from HCFA.

Response: We do not believe that PROs should decide when identifiers are to be removed from confidential information because HCFA may require

access to this information for longer periods than a PRO. Therefore, we are retaining this provision.

2. Public notice of PRO information.

Comment: Several commenters opposed the proposed requirements in § 476.116 concerning publication in the newspaper and notification to individual patients, practitioners, and institutions of the availability of PRO information because there is no statutory requirement for this notice and because they believe it could lead to PROs acting as clearinghouses for confidential information. Several commenters were also concerned about requiring notice to individuals and institutions under review, viewing this as cumbersome and resulting in unnecessary paperwork for the PRO.

Response: We agree with the commenters concerning publication of a newspaper notice and are amending § 476.116 of the regulations by deleting this requirement to avoid any possibility of inadvertently placing a clearinghouse function on a PRO. However, we are retaining the requirement that PROs notify patients, practitioners, and institutions under review concerning the type of information collected and its availability.

Although there is no specific statutory requirement for such notification, we believe these provisions are in keeping with recognized practices to assure that individuals are aware of information collected about them.

D. Disclosure of Confidential Information

1. To the Department.

Note.—A question was raised during the review of comments as to whether the requirement for disclosure to the Department under § 476.130 included the disclosure of patient records to Administrative Law Judges of the Social Security Administration. We wish to clarify that ALJs as part of the Department may request and obtain from the PROs these patient records.

Comment: Fifty-six commenters expressed concern that information or reports disclosed by the PRO to the Department would then be subject to redisclosure under the Freedom of Information Act (FOIA) (5 U.S.C. 552).

Response: We understand the commenter's concern. It is true that Federal agencies are subject to the provisions of the FOIA. However, the reports routinely submitted to HCFA do not identify patients or practitioners. Also, sensitive information such as quality review studies and PRO deliberations are accessible to the Department in very limited circumstances. Since the Department generally cannot request that this

information be sent to it, this information cannot routinely be disclosed by the Department. Moreover, the FOIA protects personal privacy by exempting from compulsory disclosure information contained in "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy" (5 U.S.C. 552(b)(6)). Also, the Department's regulations protect individual privacy under 45 CFR 5.16 and 5.71. We have amended regulations located at § 476.130 to clarify that the Department's access to PRO information is limited by the disclosure provisions for PRO deliberations and quality review study information contained in §§ 476.139(a) and 476.140.

2. Disclosure about patients.

Comment: Several commenters requested that we modify the proposed § 476.132(b)(1) to apply the proposed 15-day physician notification period required when a request is not in connection with denial cases to denial cases as well.

Response: We do not believe this is necessary because the appeal and reconsideration process assures proper physician notice and opportunity to comment.

Comment: One commenter was concerned that, in determining whether released information would harm a mentally ill patient, the PRO should give more consideration to the medical opinion of psychiatrists.

Response: According to the proposed § 476.132(b)(2) (§ 476.132(a)(2) of these final regulations), the attending physician decides whether release of the requested information would harm the patient. If the attending physician feels that another specialist should be consulted, he or she may do so. For example, if a case involved a mentally ill patient, the attending physician would be free to consult with a psychiatrist. However, the final decision to release the requested information will remain with the attending physician. We do not believe any change regarding this issue is warranted. However, we have changed the regulations to replace the term "physician" with "attending practitioner" in setting forth who can decide whether information would harm the patient.

Comment: The proposed rule in § 476.132 requires the PRO to provide patient information to the patient or to an individual designated by the PRO as the patient's representative if the patient is incompetent. One commenter wanted to know how "patient representative" is defined. Five others believe the PRO should rely on the hospital medical

record for determining who is responsible. One commenter questioned whether the PRO should decide who is competent. Finally, five commenters felt that the PRO has no authority for providing patients with their records.

Response: We are adding a definition of "patient representative" to the definition section of this subpart (§ 476.101(b)). "Patient representative" means an individual designated by the patient, in writing, as authorized to request and receive PRO information that would otherwise be disclosable to that patient, or an individual identified by the PRO in accordance with § 476.132(c)(3) when the beneficiary is mentally, physically or legally unable to designate. We are also modifying § 476.132(c)(3) to indicate that when a patient is unable to designate a representative, the PRO must first rely on the medical record to determine who is responsible. If the name of the responsible person is not recorded in the medical record, then the PRO may rely upon the attending practitioner for information. If the attending practitioner is unable to identify a responsible person, then the PRO must make a determination based on other reliable information. As to the determination of patient competency, we believe such a determination can be made by the PRO based on the documentation provided in the medical record. With regard to comments concerning patient records, the authority under which a PRO may provide patients with their records is inherent in its responsibilities under Title XI to provide patients with information relating to denial decisions and reconsiderations.

3. Verification and amendment of PRO information.

Comment: Several commenters wanted to know the types of information to be verified by the PRO for accuracy and also clarification of how the PRO will verify this information (§ 476.134). One commenter thought there was no recourse for the individual or institution if the PRO disagrees with a proposed amendment. Another commenter said that when the PRO disagrees with an amendment, the PRO should include the reasons given for the proposed amendment along with reasons for refusal.

Response: A description of the information to be verified and the methods by which PROs will verify its accuracy will be specified in the PRO contracts and in administrative guidelines. We do not believe it is appropriate to include these details in the regulations. We agree with the request that the reasons for the requested amendment be included along

with the reasons for refusal. Section 476.134 of the regulations has been amended to require that a statement of the reasons for the request be included with the disclosed information as well as the reasons for refusal. We believe this will provide sufficient recourse for an individual or institution should a PRO disagree with a requested amendment.

4. Disclosure necessary to perform review responsibilities.

Comment: One commenter believed that HCFA should impose stringent restrictions concerning redisclosure of PRO information to subcontractors, consultants, and medical review boards.

Response: We believe that § 476.107. Limitations on redisclosure, assures adequate protection for the redisclosure of confidential information; therefore, we believe that no changes in the regulations are necessary.

5. Disclosure to intermediaries and carriers.

Comment: One commenter believed that there was no need for intermediaries and carriers to obtain copies of records from the PRO. The commenter believed that if they needed to review records, they should do so onsite at the PRO.

Response: We believe it is both necessary and appropriate for intermediaries and carriers to receive copies of records from PROs when they are making coverage determinations for payment of claims. However, we believe that the number of cases for which copies of records will be requested will be few.

6. Optional disclosure of confidential information.

Comment: Five commenters were concerned that the PRO may release confidential information without a request to do so, also indicating that section 1160(b) of the Act allows disclosure of information identified as necessary by fraud and abuse agencies, public health agencies, and licensing and certification agencies, but only upon request (with the exception of cases where there may be a substantial risk to the public health).

Response: While the statute states explicitly that disclosure by the PRO without request is allowed in cases involving substantial risk to the public health (section 1160(b)(1)(B)(ii)), section 1160(a)(2) of the Act authorizes the Secretary to issue regulations that permit additional disclosures to assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care. We believe that PROs should be permitted to, and have an obligation to, disclose information to agencies without

a request when the situation warrants. For example, whenever the PRO determines that a case may involve fraud or abuse, the case should be referred to fraud and abuse agencies to protect patients and Medicare funds.

Comment: One commenter stated that PROs may be liable for providing confidential information to fraud and abuse agencies, without a request, if, for example, the recipient agency determines that no illegal activities occurred (§ 476.137).

Response: It is our opinion that a PRO could not be held liable for such a disclosure so long as the disclosure is made in accordance with these regulations.

HCFA believes that regulations are not the proper vehicle for dealing with this type of litigation but that each suit must be dealt with on a case-by-case basis.

Comment: One commenter thought that disclosure to State governmental agencies should include disclosure to State agencies responsible for administering Title XIX (Medicaid) funds.

Response: Section 1160 of the Act does not address disclosure to State agencies administering Title XIX funds. However, HCFA will notify Medicaid State agencies concerning sanctions. Therefore, we are making no changes to this section of the regulations.

7. Disclosure to the courts.

Comment: Two commenters questioned whether proposed § 476.138(c) (now § 476.138(a)(3)) which states that patient records in the possession of a PRO are not subject to subpoena or discovery in a civil action conflicts with § 476.107(i) and (j) which permit certain redisclosures of confidential information.

Response: Section 1160(d) of the Act only provides protection from subpoena or discovery in a civil action for patient records in the possession of the PRO. Furthermore, section 1160(b) of the Act permits the redisclosure of such information by certain governmental agencies when the redisclosure is made in a judicial, administrative or other legal proceeding resulting from the agency's investigation. Therefore, no changes are being made to the regulations as a result of these comments.

Comment: One commenter recommended that "civil action" in the proposed §§ 476.138(c) (§ 476.138(a)(3) of these final regulations) and 476.140(d) be defined and that the definition include civil arbitration. The commenter requested this change because of a court decision which held that a State agency

chartered with responsibility for disciplinary sanctions could subpoena the confidential records of a medical review committee (a group exercising functions similar to those of PROs).

Response: We agree with the commenter. Congress precluded patient-identified records held by PROs from subpoena or discovery in civil actions. We, therefore, believe it would be within congressional intent to preclude patient-identified records from subpoena or discovery in a variety of civil actions, including administrative, judicial or arbitration proceedings.

We also believe that quality review study information with identifiers held by PROs should be protected in the same manner as other patient identified information because quality review study information is based on medical records and consists of patient identified information. Therefore, we are amending regulations at §§ 476.138(a)(3) and 476.140(d) (redesignated as (e)) to prohibit the disclosure of patient-identified records and quality review study information that identifies patients in a civil action, including an administrative, judicial or arbitration proceeding. These restrictions do not apply to the Department's administrative subpoena authority under the Social Security Act, the Inspector General's subpoena authority, or to disclosures to the General Accounting Office as necessary to carry out its statutory responsibilities.

8. Disclosure of PRO deliberations and decisions.

Comment: Two commenters stated that practitioners and providers should have access to PRO deliberations or at least to an indepth narrative of the deliberations, especially for sanctions. One commenter suggested adding that deliberations are not subject to subpoena or discovery in a civil action.

Response: In response to the first comment, the strict limitations on disclosure of PRO deliberations set forth at § 476.139 are necessary to encourage frank discussions among those involved. Also, a PRO may disclose the reasons for PRO decisions (see § 476.139(b)). In response to the second comment, there is no statutory basis for protecting PRO deliberations from subpoena or discovery in a civil action. Therefore, we are not changing the regulations.

Comment: One commenter questioned whether § 476.139 supersedes other sections of these regulations addressing disclosure of confidential information when the information involves PRO deliberations (§§ 476.132, 476.133, 476.137, and 476.138). Another stated that if the reasons for PRO decisions are disclosed, they should not identify

practitioners or providers. Other commenters believed that the OIG and General Accounting Office (GAO) should have access to PRO deliberations other than just the deliberations included in sanction reports.

Response: With regard to the comment concerning PRO deliberations, § 476.139 is controlling over the disclosure requirements in other sections of the regulations. Each of the sections cited by the commenter have been amended to clarify this fact. Regarding the protection of practitioners and providers when the reasons for a PRO decision are disclosed, § 476.139(b) addresses this concern because it states that reasons for PRO decisions may be disclosed only if the opinions or judgments of a particular individual cannot be discerned. We are revising § 476.139(b) to clarify that opinions or judgments of a particular individual, patient, or practitioner cannot be discerned and are making a technical change to § 476.139(b) to revise the heading to "Reasons for PRO decisions", so that it more accurately describes the information contained in that paragraph.

Regarding the comment on OIG and GAO access to PRO deliberations, we agree and are changing § 476.139 to make clear that the OIG and GAO have access to PRO deliberations to carry out their statutory responsibilities. This change includes offsite access to provide for those very limited circumstances where offsite access would be essential to the carrying out of the Inspector General's responsibility to eliminate fraud, abuse and waste in HHS programs and the General Accounting Office's statutory responsibilities.

We have made several other changes to § 476.139 which are discussed more fully under section IV. Changes to the Regulations.

9. Disclosure of quality review study information.

Comment: A number of commenters were concerned that providers would have access to quality review studies containing identifiers of particular providers.

Response: We agree. As worded, § 476.140(b) would have permitted a PRO to disclose quality review study information to all institutions and practitioners involved in the study with all identifiers included. We are therefore amending this section to prevent disclosure of information identifying a particular institution or practitioner to other institutions or practitioners.

We are also making several technical changes to § 476.140 as specified in section IV., Changes to the Regulations.

Comment: Two commenters were concerned that there is no statutory basis for release of quality review studies to accreditation, licensure, and certification agencies.

Response: Section 1180(b)(1)(C) of the act requires the PROs, in accordance with procedures and safeguards established by the Secretary, to provide data and information which may identify specific providers and practitioners to these agencies.

10. Practitioner-identified information.

Comment: The proposed rule requested comments regarding the advisability of releasing practitioner-identified information.

Most commenters concur with our proposal for maintaining the confidentiality of practitioner-identified information. There is concern that the release of such data could be misinterpreted and misunderstood. Several other commenters concurred as well, but would also maintain the confidentiality of institution-identified information.

One commenter stated that our proposal to reveal practitioner-identified information was in violation of the statute and indicates the extent to which the proposed regulations favor public disclosure over the protection of individual privacy.

A number of commenters favor increased access to practitioner-identified information, believing that such information is necessary to assist employees and consumers in choosing physicians, to control costs, and to assist efforts aimed at increasing the quality of care.

Commenters also expressed concern that limiting the disclosure of practitioner-identified information may serve as a precedent for limiting disclosure of other information. One commenter would modify § 476.133(b) to allow a PRO, on its own initiative, to disclose to an institution, practitioner-identified information pertaining to a physician's practice or performance patterns in the institution.

There were also several comments on practitioner-identified information concerning § 476.130 (which calls for disclosure of information to the Department). Commenters stated that disclosure may hinder physician cooperation in the review process. One commenter indicated that blanket authorization for the PRO to release practitioner-identified information to the Department serves no purpose and should be limited to situations where a clear pattern of potential abuse is evident.

Response: While a number of commenters believe that general disclosure of practitioner-identified information is necessary to control health care costs and to assist consumers and others in health-related matters, we continue to believe that general disclosure is inappropriate. The potential is great for such information to be misinterpreted and misused. Public disclosure of PRO data about identified physicians could be misleading, perhaps with significant damage to reputations and practices. Releasing information that may damage the reputation of practitioners is particularly troublesome because even if the information is completely accurate, it may not fully describe all the factors relevant to a practitioner's practice. For example, mortality figures for coronary surgery may be higher for Surgeon A than for Surgeon B. However, this may be because Surgeon A is performing more complicated procedures or because Surgeon A's patients are on the average sicker than Surgeon B's patients. Furthermore, the general disclosure of practitioner-identified information could reduce the effectiveness of the peer review process under the PRO program. Also, as mentioned earlier, the Institute of Medicine report supported limitation on disclosure of practitioner-identified information. Therefore, as proposed, we would permit the disclosure of practitioner-identified information to the individual practitioner, to the institution where the individual practices, or, with the practitioner's consent, to any designated person, agency or organization. Practitioner-identified information may also be disclosed to recognized Federal and State agencies in certain situations (§§ 476.130, 476.137 and 476.138).

11. Disclosure of sanction reports.

Comment: One commenter said that the State Medicaid agency should be advised of any possible sanction in progress by a PRO against a Medicare provider because any abuse in Medicare could have possible implications for Medicaid.

Response: Because no decision has been reached concerning sanctions in progress, the information in the PRO's possession is subject to the same disclosure limitations as any other confidential information.

12. Disclosure to research and statistical agencies.

Comment: Twenty commenters objected to the proposed rule permitting PROs to disclose confidential information on its own initiative to research and statistical agencies, stating that there is no specific statutory basis for such action. Seven commenters

believed that the PRO should have patient, and practitioner, and provider consent before releasing the information. Six said that because there is no protection from redisclosure after the information is released, patient practitioner identifiers should be deleted.

Response: The primary responsibility of a PRO is to review services provided under the Medicare program to assure that Medicare payment is made only for services that are medically necessary, delivered in the most appropriate setting, and meet professionally accepted standards of patient care quality. In order to accomplish this task, a PRO must perform preadmission review and review hospital admissions occurring within seven days of a previous discharge, every permanent cardiac pacemaker insertion, all transfers, a random sample of all Medicare admissions, day and cost outliers, and validate whether the diagnostic and procedural information reported by hospitals for DRG assignment is correct. PROs also have utilization and quality of care objectives that have to be met under the terms of their contract. The PROs, therefore, carry a heavy workload in order to fulfill their primary responsibilities.

A significant additional burden would be placed on PROs were they to routinely decide on which research or statistical agency requests for confidential information to honor.

Nevertheless, we did consider two approaches concerning PRO release of information to researchers and statisticians.

The first approach would be to require every PRO to release all PRO confidential information to a research agency upon request. The second approach would be to give the PRO the option of releasing confidential information. However, there are problems with both approaches; the mandatory method leaves the PRO with no control over the type of confidential information that may be released. The optional approach would result in inconsistent decisions among PROs as to what constitutes appropriate releases. This lack of uniformity would be unfair to patients, practitioners and researchers.

After careful consideration, we recognize that, while PRO confidential information may be helpful to some researchers, the preponderance of effects would have a significant adverse impact on PRO review. Therefore, we have decided to delete the proposed § 476.143 in its entirety.

We are redesignating proposed § 476.144 as § 476.143.

E. Cost of Duplicating Medical Records and Impact Analysis.

Comments: We received approximately 100 comments expressing concern over the costs of copying medical records requested by PROs under §§ 476.111(a) and 476.131 of the proposed regulations.

Response: We believe it is important that PROs have adequate access to medical records to enable them to carry out required activities. This includes the right to request and receive copies as they deem necessary including preadmission test records. In some cases, this will mean that the PRO will request hospitals to photocopy specific medical records and mail them to the PRO.

The prospective payment rates are computed according to the provisions of the law and are also based on the best available data at the time of computation. Administrative costs are included in the Federal and hospital specific portions of prospective payments by virtue of their being incurred and reported by hospitals for the years that represent the data bases for the prospective payment system.

Prior to the use of PROs, review of inpatient hospital services was carried out either at the hospital or offsite. Offsite review sometimes required that the hospital mail patient records to Medicare fiscal intermediaries. These costs were subsumed in the hospital's administrative costs that in turn were reflected in Medicare cost reimbursement calculations. Costs related to such activities are accounted for, in some measure, in the prospective payment base rates.

We also believe that the fiscal benefits of PRO review will compensate for any such increased costs. For example, in many cases, PROs' preadmission review activities will protect hospitals from retrospective denials. Thus, there will be trade-offs between a hospital's cost of providing medical records to PROs and a PRO's performance of review that, in many cases, may assist hospitals in avoiding unnecessary expenditures.

Comment: Five commenters stated that both a regulatory impact and a regulatory flexibility analysis were required in the NPRM, since the annual economic impact of these provisions meets the threshold criteria of Executive Order 12291 and the Regulatory Flexibility Act.

Response: We agree with the commenters that certain impacts (benefits, costs, and behavioral changes) will result from implementing this final

rule. However, we believe that our selection of policy alternatives in the implementation of the PRO program is responsive to Congressional intent and will result in net benefits to affected providers, practitioners, and beneficiaries.

Concerning their position that the annual economic impact will meet the threshold criteria of Executive Order 12291 or of the Regulatory Flexibility Act of 1980 (Pub. L. 96-354), we believe that the primary impact of this final rule will result from requiring hospitals to photocopy and send specific medical records under certain conditions (proposed §§ 476.111(a) and 476.131). In addition, as we remarked in our response to the previous comment, hospitals will experience benefits from PRO reviews, not just costs.

We estimate that in FY 1985 hospitals will incur about \$9.8 million in additional operating expenses to photocopy records and mail them to PROs. This estimate assumes that PROs will perform retrospective offsite review on about 7 percent of the Medicare discharges in FY 1985. We estimate that the number of Medicare discharges, and thus the number of patient records to be reviewed offsite, will not increase significantly in FY 1986. Thus, the hospitals will incur no significant additional expenses above the FY 1985 estimated costs of \$9.8 million. We estimate that these total costs will result in an average per hospital cost of less than \$2,000 each year.

Because the photocopying provision, which is the provision that is most likely to have the greatest impact, does not meet any of the threshold requirements, we have determined that neither a regulatory impact or a regulatory flexibility analysis is required.

IV. Changes to the Regulations

Based on comments received and other considerations, we are making the following substantive changes to the proposed rules. We also have made technical changes to the proposed regulations in order to correct drafting and typographical errors and to clarify certain sections.

A. General Provisions

We are adding the definition of "Utilization and Quality Control Peer Review Organization (PRO)" to the definition section for 42 CFR Chapter IV located at § 400.200. We are adding this term because we make frequent references to it throughout 42 CFR Chapter IV.

In § 476.101(b) that includes the definitions for Part 476, we are making the following changes:

- We are modifying the definition of "abuse" to make it more consistent with the PRO sanction process.

- We are amending the definition of "confidential information". The phrase "Quality review study information which identifies patients" has been modified to read "Quality review studies which identify patients, practitioners or institutions".

- We are deleting the definition of "Medicare patient" because we believe that the term is self-explanatory.

- We are deleting the definition of "subcontracted institution" and adding a definition of "subcontractor" that is consistent with the definition contained in § 466.1 of the proposed regulations concerning a PRO's assumption of review that was published on July 17, 1984 (49 FR 29036).

- We are adding the definitions of "health care facility", "non-facility organization" and "patient representative".

- We are revising the definition of "practitioner" to conform to the definition contained in the proposed regulations concerning a PRO's assumption of review.

- We are adding language to the definition of "PRO deliberations" to further clarify its meaning.

- We are changing the definition of "quality review study" (QRS) to specify that a QRS for purposes of these regulations means only a QRS conducted by or for a PRO and to conform to the definition of QRS contained in § 466.1 of final regulations concerning a PRO's assumption of review published elsewhere in this issue of the Federal Register.

- We are adding definitions for "aggregate statistical data", "implicitly identify(ies)" and "PRO interpretations and generalizations on the quality of health care" to further clarify these terms.

These final rules amend the proposed regulations located at § 476.104 regarding the procedures for disclosure to clarify that the requirements for providing a notice of the disclosure specified in § 476.105 also apply. We are further revising § 476.104 to delete the requirement that information may not be redisclosed without written consent from the person or institution to which it pertains. This provision was not consistent with the proposed limits pertaining to redisclosure set forth in § 476.107.

In § 476.105 we are making the following changes:

- We are amending the notification requirement from 15 calendar days to 30 calendar days.

- We are clarifying the term "not routinely prepared for PRO use" contained in § 476.105(a).

- We are amending § 476.105(b)(2) to clarify that a PRO must notify a practitioner or institution of the PRO's intent to disclose information about that practitioner or institution except in cases involving fraud or abuse or an imminent danger to individuals or the public health. This revision is necessary to make § 476.105 conform to § 476.106.

These final rules amend proposed regulations located at § 476.106(b) to require that all investigative agencies, except the OIG and GAO, must specify in writing to the PRO that the information requested is related to a potentially prosecutable criminal offense.

We are amending regulations at § 476.107 by adding a paragraph (k) that would expand redisclosure as necessary for the Office of the Inspector General to carry out its statutory responsibilities. Paragraph (f) has also been amended to clarify that redisclosure is permissible as necessary for the GAO to carry out its statutory responsibilities. Regulations located at § 476.107 (g) and (h) are clarified to indicate that an institution, patient, or practitioner may disclose information pertaining to them provided that no other specific patient or practitioner is identified in that information. We are also amending § 476.107(i) to delete reference to Federal and State health planning agencies with respect to redisclosure of certain information.

We are amending regulations located at § 476.108 to correct a grammatical error with respect to the penalty for unauthorized disclosure of information.

B. PRO Access to Information

We are amending regulations located at § 476.111 to:

- Clarify that PROs may obtain specific non-Medicare patient records relating to review performed under non-Medicare contracts held by the PRO if authorized by those patients in accordance with State law; and

- Redesignate paragraph (b) as (c) and modify it to specify that a PRO may have access to and obtain records of non-Medicare patients who are not covered under a private review contract held by the PRO only in connection with its quality review responsibilities and only if authorized by the institution or practitioner.

The proposed regulations located at § 476.112 are amended to specify that PROs can only have access to Medicare records and information held by carriers or intermediaries.

We are clarifying in § 476.114 of the regulations that the requirements of 44 U.S.C. Chapter 35 only apply to a PRO's collection of information as a federal contractor.

C. PRO Responsibilities

Section § 476.115(d)(1) is amended to delete "is undergoing" from the reference to training programs. We further amended § 476.115 by revising paragraph (e) to clarify that patient records must also be purged of personal identifiers.

We are also amending regulations located at § 476.116 to delete the requirement for publication of notice in a newspaper of the availability of certain PRO information.

D. Disclosure of Nonconfidential Information

We are amending § 476.120 to clarify that the procedures for disclosure and notice of the disclosure specified in §§ 476.104 and 476.105 apply to the information subject to disclosure under § 476.120. We are also clarifying that the PRO must disclose certain aggregate statistical information to Federal or State health planning agencies.

E. Disclosure of Confidential Information

We are amending regulations at § 476.130 to specify that a PRO's disclosure of information to the Department is limited by §§ 476.139(a) and 476.140 of the regulations.

We are amending regulations located at § 476.132 to:

- Clarify that when patient identified information is disclosed to a specific patient or patient's representative, all other practitioner or patient identification must be removed;
- Clarify that the patient representative must be designated by the patient;

• Replace the term "physician" with "attending practitioner" in setting forth who can decide whether disclosure of information would harm the patient;

• Clarify that in the case of a disclosure request from a patient or the patient's representative regarding an initial denial determination, a PRO must release the information in accordance with the procedures for disclosure under § 473.28. The PRO is not required to notify the patient's practitioner of the request;

• Clarify that the regulations located at §§ 476.139(a) and 476.140 regarding the disclosure of PRO deliberations and quality review study information control over the disclosure provisions of § 476.132; and

- Establish the procedures by which a PRO determines who is responsible for a patient in cases in which the direct disclosure of information to a patient could harm the patient.

We are amending regulations located at § 476.133 to clarify that the disclosure of information about practitioners, reviewers and institutions under this section is also subject to requirements specified in other sections of these regulations. Additionally, we are specifying that the information disclosed by the PRO under this section concerning a particular practitioner or reviewer must not identify other individuals.

Regulations located at § 476.134 are amended to require that when a PRO disagrees with a request for amendment to PRO information, it must include with any disclosure of that information the reasons for the requested amendment as well as the reasons for refusal.

We are amending the regulations at §§ 476.136, 476.137 and 476.138 to specify that the provisions relating to the disclosure of PRO deliberations and quality review study information (§§ 476.139(a) and 476.140) control over the provisions for disclosure in §§ 476.136, 476.137 and 476.138.

We are further amending the regulations located at § 476.138 to clarify that, as provided in section 1160(b)(1)(C) of the Act, a PRO must disclose information to Federal and State agencies only to the extent required by the agency to carry out a function which is within the jurisdiction of the agency under Federal or State law. Also, we have revised the language at § 476.138(a)(3) (this was § 476.138(b) of the proposed regulations) referring to "imminent danger" to conform with section 1160(b)(1)(B) of the Act that refers to "a substantial risk to the public health".

We are amending regulations at §§ 476.138 and redesignating § 476.140(d) to (e) to preclude the use of a subpoena or other discovery methods in a variety of civil actions, including administrative, judicial or arbitration proceedings in order to obtain patient-identified records from a PRO. The restriction does not apply to the Department's administrative subpoena authority under the Social Security Act, the Inspector General's subpoena authority, or to disclosures to the General Accounting Office as necessary to carry out its statutory responsibilities.

We are amending regulations at § 476.139 to make several changes. First, § 476.139 is revised to insure that the opinions or judgments of a particular patient or practitioner cannot be identified. Second, we are amending

§ 476.139 of the regulations to specify that the OIG and GAO have access to PRO deliberations to carry out their statutory responsibilities including offsite access for those very limited circumstances where such access is essential. PRO deliberations are not disclosable, either in written form or through oral testimony, in connection with the administrative hearing or review of a beneficiary's claim. We believe this is necessary so as not to inhibit the frank and open discussions between peer reviewers when they are discussing a beneficiary's case. We have also clarified the regulations to specify that a PRO must disclose, if requested, in connection with the administrative hearing or review of a beneficiary's claim, the reasons for PRO decisions. The PRO must include the detailed facts, findings and conclusions that support the PRO's determination. The PRO must insure that the opinions or judgments of a particular individual or practitioner cannot be identified through the materials that are disclosed.

We are amending regulations at § 476.140(a)(1) to make the language consistent with that in § 476.107 (f), (i) and (j) regarding the responsibilities of various Federal, State and local agencies and to make it consistent with the changes made by the new paragraph (b) discussed below. We are also revising § 476.140 (a)(2) and (3) to limit further the onsite review of quality review studies. We are redesignating the proposed § 476.140 (b) to (c) and amending it to clarify that PROs may disclose certain quality review information offsite and to prevent the disclosure of quality review study information which identifies a particular institution or practitioner to other institutions or practitioners. Paragraphs (c) and (d) are redesignated as (d) and (e) respectively. In addition, a new paragraph (b) is being added to require PRO disclosure, both onsite and offsite, of quality review study information to the OIG and GAO as necessary to carry out their statutory responsibilities.

We are amending § 476.141 to clarify that the procedures for disclosure and notice of the disclosure specified in §§ 476.104 and 476.105 apply to the information disclosed under § 476.141.

We are amending regulations to delete § 476.143 in its entirety and to redesignate the proposed § 476.144 as § 476.143.

V. Impact Analysis

Executive Order (E.O.) 12291 requires us to prepare and publish a regulatory impact analysis for any regulations that are likely to have an annual effect on

the economy of \$100 million or more, cause a major increase in costs or prices, or meet other threshold criteria that are specified in section 1(b) of the Executive Order. In addition, the Regulatory Flexibility Act, Pub. L. 96-354, requires us to prepare and publish a regulatory flexibility analysis for regulations unless the Secretary certifies that the regulations will not have a significant economic impact on a substantial number of small entities. Under both the Executive Order and the Regulatory Flexibility Act, such analyses must, when prepared, show that the agency issuing the regulations has examined alternatives that might minimize an unnecessary burden or otherwise ensure that the regulations are cost-effective.

A. Executive Order 12291

In section III. E. of the preamble, we respond to 100 commenters concerning the potential cost of duplicating and sending patient records to a PRO. In that section we also address comments about the absence of an initial regulatory impact analyses in the proposed rule. We believe that our earlier determination that an E.O. 12291 impact analysis was not required was correct and that our responses in section III. E. fully address the questions raised by the commenters.

In response to other public comments, we have made changes to some of the provisions contained in the proposed rule. We believe that these changes will simplify and clarify our intended policies; and, that, taken as a whole, this rule will not result in an annual economic impact of \$100 million annually, or that meets the threshold criteria of section 1(b) of the Executive Order. Thus, a final regulatory impact analysis is not required. It is our contention that these changes will, in fact, be beneficial to the PROs, providers, practitioners and beneficiaries by providing clarity in our policies and procedures that govern the acquisition, protection and disclosure of information obtained or generated by a PRO.

Regulatory Flexibility Act

As noted in the Executive Order discussion, we have responded to comments concerning the potential impact on providers resulting from these provisions. In Section III. E. we state most hospitals will incur some additional cost in duplicating patient records and information. However, for the reasons noted in that section of our response, we believe that the increase in cost resulting from these changes will

not be significant, on average, for a substantial number of providers.

Also, for the purposes of this final rule, we have examined the changes noted in this preamble and conclude that the impact of these changes will also not be significant. These changes are primarily clarifications of our policies and procedures and, as such, will not result in additional costs and, in fact, should be beneficial to providers, practitioners, PROs and beneficiaries. Therefore, we have determined, and the Secretary certifies under 5 U.S.C. 605(b), enacted by the Regulatory Flexibility Act of 1980 (Pub. L. 96-354), that this final rule, taken as a whole, will not result in a significant impact on a substantial number of small entities.

VI. Information Collection Requirements

Sections 476.105, 476.116, and 476.134 of this rule contain information collection requirements. They are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507). The public is not required to comply with these requirements until OMB approves them under the Paperwork Reduction Act of 1980. Comments on these requirements should be sent directly to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, Washington, D.C., Attention: Fay Iudicello. A notice will be published in the Federal Register when approval is obtained.

List of Subjects

42 CFR Part 400

Health facilities, Health maintenance organizations (HMO), Medicaid, Medicare.

42 CFR Part 476

Health care, Health professions, Health records, Privacy, Professional Standards Review Organizations (PSRO); and Utilization and Quality Control Peer Review Organizations (PROs).

42 CFR Chapter IV is amended as set forth below:

A. The table of contents is amended by revising the title of Part 476 in Subchapter D to read as follows:

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

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SUBCHAPTER D—PEER REVIEW ORGANIZATIONS

• • • • •

PART 476—ACQUISITION, PROTECTION, AND DISCLOSURE OF PEER REVIEW INFORMATION

• • • • •

PART 400—INTRODUCTION; DEFINITIONS

The authority citation for Part 400 reads as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

B. In Part 400, § 400.200 is amended by adding, in alphabetical order, the definition of "Utilization and Quality Control Peer Review Organization (PRO)" to read as follows:

§ 400.200 General definitions.

• • • • •

"Utilization and Quality Control Peer Review Organization" (PRO) means an organization that has a contract with HCFA to review, under Part B of Title XI of the Act, the health care services or items furnished or proposed to be furnished to Medicare beneficiaries.

C. Part 476 is amended as set forth below:

1. The title of Part 476 is revised to read as follows:

PART 476—ACQUISITION, PROTECTION, AND DISCLOSURE OF PEER REVIEW INFORMATION

2. The table of contents is amended to reflect the establishment of a new Subpart A—"Professional Standards Review Organizations", to include current §§ 476.1–476.4. The table of contents is further amended by adding a new Subpart B and revising the authority citation to read as follows:

Subpart B—Utilization and Quality Control Peer Review Organizations (PROs)

General Provisions

Sec.

- 476.101 Scope and definitions.
- 476.102 Statutory bases for acquisition and maintenance of information.
- 476.103 Statutory bases for disclosure of information.
- 476.104 Procedures for disclosure by a PRO.
- 476.105 Notice of disclosures made by a PRO.
- 476.106 Exceptions to PRO notice requirements.
- 476.107 Limitations on redisclosure.
- 476.108 Penalties for unauthorized disclosure.
- 476.109 Applicability of other statutes and regulations.

PRO Access to Information

- 476.111 PRO access to records and information of institutions and practitioners.

Sec.

- 476.112 PRO access to records and information of intermediaries and carriers.
- 476.113 PRO access to information collected for PRO purposes.
- 476.114 Limitations on data collection.

PRO Responsibilities

- 476.115 Requirements for maintaining confidentiality.
- 476.116 Notice to individuals and institutions under review.

Disclosure of Nonconfidential Information

- 476.120 Information subject to disclosure.
- 476.121 Optional disclosure of nonconfidential information.

Disclosure of Confidential Information

- 476.130 Disclosure to the Department.
- 476.131 Access to medical records for the monitoring of PROs.
- 476.132 Disclosure of information about patients.
- 476.133 Disclosure of information about practitioners, reviewers and institutions.
- 476.134 Verification and amendment of PRO information.
- 476.135 Disclosure necessary to perform review responsibilities.
- 476.136 Disclosure to intermediaries and carriers.
- 476.137 Disclosure to Federal and State enforcement agencies responsible for the investigation or identification of fraud or abuse of the Medicare program.
- 476.138 Disclosure for other specified purposes.
- 476.139 Disclosure of PRO deliberations and decisions.
- 476.140 Disclosure of quality review study information.
- 476.141 Disclosure of PRO interpretations on the quality of health care.
- 476.142 Disclosure of sanction reports.
- 476.143 PRO involvement in shared health data systems.

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302). Subpart A is also issued under sec. 150 of Pub. L. 97-248, 42 U.S.C. 1320c note. Subpart B is also issued under secs. 1154(a), 1156(a) and 1160 of the Social Security Act, 42 U.S.C. 1320c-3(a), 1320c-5(a), and 1320c-9.

3. A new Subpart B is added to read as follows:

Subpart B—Utilization and Quality Control Peer Review Organizations (PROs)**General Provisions****§ 476.101 Scope and definitions.**

(a) *Scope.* This subpart sets forth the policies and procedures governing—

(1) Disclosure of information collected, acquired or generated by a Utilization and Quality Control Peer Review Organization (PRO) (or the review component of a PRO subcontractor) in performance of its responsibilities under the Act and these regulations; and

(2) Acquisition and maintenance of information by a PRO to comply with its responsibilities under the Act.

(b) *Definitions.* As used in this part: "Abuse" means any unlawful conduct relating to items or services for which payment is sought under Title XVIII of the Act.

"Aggregate statistical data" means any utilization, admission, discharge or diagnostic related group (DRG) data arrayed on a geographic, institutional or other basis in which the volume and frequency of services are shown without identifying any individual.

"Confidential information" means any of the following:

(1) Information that explicitly or implicitly identifies an individual patient, practitioner or reviewer.

(2) Sanction reports and recommendations.

(3) Quality review studies which identify patients, practitioners or institutions.

(4) PRO deliberations.

"Health care facility" or "facility" means an organization involved in the delivery of health care services or items for which reimbursement may be made in whole or in part under Title XVIII of the Act.

"Implicitly identify(ies)" means data so unique or numbers so small so that identification of an individual patient, practitioners or reviewer would be obvious.

"Non-facility organization" means a corporate entity that: (1) is not a health care facility; (2) is not a 5 percent or more owner of a facility; and (3) is not owned by one or more health care facilities in the PRO area.

"Patient representative" means—(1) An individual designated by the patient, in writing, as authorized to request and receive PRO information that would otherwise be disclosable to that patient; or (2) and individual identified by the PRO in accordance with § 476.132(c)(3) when the beneficiary is mentally, physically or legally unable to designate a representative.

"Practitioner" means an individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients.

"PRO deliberations" means discussions or communications (within a PRO or between a PRO and a PRO subcontractor) including, but not limited to, review notes, minutes of meetings and any other records of discussions and judgments involving review matters regarding PRO review responsibilities and appeals from PRO determinations, in which the opinions of, or judgment

about, a particular individual or institution can be discerned.

"PRO information" means any data or information collected, acquired or generated by a PRO in the exercise of its duties and functions under Title XI Part B or Title XVIII of the Act.

"PRO interpretations and generalizations on the quality of health care" means an assessment of the quality of care furnished by an individual provider or group of providers based on the PRO's knowledge of the area gained from its medical review experience (e.g., quality review studies) and any other information obtained through the PRO's review activities.

"PRO review system" means the PRO and those organizations and individuals who either assist the PRO or are directly responsible for providing medical care or for making determinations with respect to the medical necessity, appropriate level and quality of health care services that may be reimbursed under the Act. The system includes—

(1) The PRO and its officers, members and employees;

(2) PRO subcontractors;

(3) Health care institutions and practitioners whose services are reviewed;

(4) PRO reviewers and supporting staff; and

(5) Data support organizations.

"Public information" means information which has been disclosed to the public.

"Quality review study" means an assessment, conducted by or for a PRO, of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up.

"Quality review study information" means all documentation related to the quality review study process.

"Reviewer" means review coordinator, physician, or other person authorized to perform PRO review functions.

"Sanction report" means a report filed pursuant to section 1156 of the Act and Part 474 of this chapter documenting the PRO's determination that a practitioner or institution has failed to meet obligations imposed by section 1156 of the Act.

"Shared health data system" means an agency or other entity authorized by Federal or State law that is used by the PRO review system to provide information or to conduct or arrange for the collection, processing, and dissemination of information on health care services.

"Subcontractor" means a facility or a non-facility organization under contract

with a PRO to perform PRO review functions.

§ 476.102 Statutory bases for acquisition and maintenance of information.

(a) Section 1154(a)(7)(C) of the Act requires PROs to the extent necessary and appropriate to examine the pertinent records of any practitioner or provider of health care services for which payment may be made under Title XVIII of the Act.

(b) Section 1154(a)(9) of the Act requires PROs to collect and maintain information necessary to carry out their responsibilities under the Act.

(c) Section 1156(a)(3) of the Act requires health care practitioners and providers to maintain evidence of the medical necessity and quality of health care services they provide to Medicare patients as required by PROs.

§ 476.103 Statutory bases for disclosure of information.

(a) Section 1154(a)(10) of the Act requires PROs to exchange information with intermediaries and carriers with contracts under sections 1816 and 1842 of the Act, other PROs, and other public or private review organizations as appropriate.

(b) Section 1160 of the Act provides that PRO information must be held in confidence and not be disclosed except where—

(1) Necessary to carry out the purpose of Title XI Part B of the Act;

(2) Specifically permitted or required under this subpart;

(3) Necessary, and in the manner prescribed under this subpart, to assist Federal and State agencies recognized by the Secretary as having responsibility for identifying and investigating cases or patterns of fraud or abuse;

(4) Necessary, and in the manner prescribed under the subpart to assist Federal or State agencies recognized by the Secretary as having responsibility for identifying cases or patterns involving risks to the public health;

(5) Necessary, and in the manner prescribed under this subpart to assist appropriate State agencies having responsibility for licensing or certification of providers or practitioners; or

(6) Necessary, and in the manner prescribed under this subpart to assist Federal or State health planning agencies by furnishing them aggregate statistical data on a geographical institution or other basis.

§ 476.104 Procedures for disclosure by a PRO.

(a) *Notice to accompany disclosure.*

(1) Any disclosure of information under the authority of this subpart is subject to the requirements in § 476.105 relating to the providing of a notice of the disclosure.

(2) Disclosure of confidential information made under the authority of this subpart, except as provided in § 476.106, must be accompanied by a written statement informing the recipient that the information may not be redisclosed except as provided under § 476.107 that limits redisclosure.

(b) *PRO interpretations.* A PRO may provide a statement of comment, analysis, or interpretation to guide the recipient in using information disclosed under this subpart.

(c) *Fees.* A PRO may charge a fee to cover the cost of providing information authorized under this subpart. These fees may not exceed the amount necessary to recover the cost to the PRO for providing the information.

(d) *Format for disclosure of public information.* A PRO is required to disclose public information (§ 476.120(a)(6)) only in the form in which it is acquired by the PRO or in the form in which it is maintained for PRO use.

(e) *Medicare provider number.* A PRO must include the provider identification number assigned by Medicare program on information that HCFA requests.

§ 476.105 Notice of disclosures may be made by a PRO.

(a) *Notification of the disclosure of nonconfidential information.* Except as permitted under § 476.106, at least 30 calendar days before disclosure of nonconfidential information, the PRO must notify an identified institution of its intent to disclose information about the institution (other than reports routinely submitted to HCFA or Medicare fiscal intermediaries, or to or from PRO subcontractors, or to or from the institution) and provide the institution with a copy of the information. The institution may submit comments to the PRO that must be attached to the information disclosed if received before disclosure, or forwarded separately if received after disclosure.

(b) *Notification of the disclosure of confidential information.* (1) A PRO must notify the practitioner who has treated a patient, of a request for disclosure to the patient or patient representative in accordance with the requirements and expectations to the requirements for disclosure specified under § 476.132.

(2) A PRO must notify a practitioner or institution of the PRO's intent to disclose information on the practitioner or institution to an investigative or

licensing agency (§§ 476.137 and 476.138) except for cases specified in § 476.106 involving fraud or abuse or imminent danger to individuals or the public health. The practitioner or institution must be notified and provided a copy of the information to be disclosed at least 30 calendar days before the PRO discloses the identifying information. The PRO must forward with the information any comments submitted by the practitioner or institution in response to the PRO notice if received before disclosure, or forwarded separately if received after disclosure.

§ 476.106 Exceptions to PRO notice requirements.

(a) *Imminent danger to individuals or public health.* When the PRO determines that requested information is necessary to protect against an imminent danger to individuals or the public health, the notification required in § 476.105 may be sent simultaneously with the disclosure.

(b) *Fraud or Abuse.* The notification requirement in § 476.105 does not apply if—

(1) The disclosure is made in an investigation of fraud or abuse by the Office of the Inspector General or the General Accounting Office; or

(2) The disclosure is made in an investigation of fraud or abuse by any other Federal or State fraud or abuse agency and the investigative agency specifies in writing that the information is related to a potentially prosecutable criminal offense.

§ 476.107 Limitations on redisclosure.

Persons or organizations that obtain confidential PRO information must not further disclose the information to any other person or organization except—

(a) As directed by the PRO to carry out a disclosure permitted or required under a particular provision of this part;

(b) As directed by HCFA to carry out specific responsibilities of the Secretary under the Act;

(c) As necessary for HCFA to carry out its responsibilities for appeals under section 1155 of the Act or for HCFA to process sanctions under section 1156 of the Act;

(d) If the health care services furnished to an individual patient are reimbursed from more than one source, these sources of reimbursement may exchange confidential information as necessary for the payment of claims;

(e) If the information is acquired by the PRO from another source and the receiver of the information is authorized under its own authorities to acquire the

information directly from the source, the receiver may disclose the information in accordance with the source's redisclosure rules;

(f) As necessary for the General Accounting Office to carry out its statutory responsibilities;

(g) Information pertaining to a patient or practitioner may be disclosed by that individual provided it does not identify any other patient or practitioner;

(h) An institution may disclose information pertaining to itself provided it does not identify an individual patient or practitioner;

(i) Governmental fraud or abuse agencies and State licensing or certification agencies recognized by HCFA may disclose information as necessary in a judicial, administrative or other formal legal proceeding resulting from an investigation conducted by the agency;

(j) State and local public health officials to carry out their responsibilities, as necessary, to protect against a substantial risk to the public health; or

(k) As necessary for the Office of the Inspector General to carry its statutory responsibilities.

§ 476.108 Penalties for unauthorized disclosure.

A person who discloses information not authorized under Title XI Part B of the Act or the regulations of this part will, upon conviction, be fined no more than \$1,000, or be imprisoned for no more than six months, or both, and will pay the costs of prosecution.

§ 476.109 Applicability of other statutes and regulations.

The provisions of 21 U.S.C. 1175 governing confidentiality of alcohol and drug abuse patients' records, and the implementing regulations at 42 CFR Part 2, are applicable to PRO information.

PRO Access to Information

§ 476.111 PRO access to records and information of institutions and practitioners.

(a) A PRO is authorized to have access to and obtain records and information pertinent to the health care services furnished to Medicare patients, held by any institution or practitioner in the PRO area. The PRO may require the institution or practitioner to provide copies of such records or information to the PRO.

(b) A PRO may obtain non-Medicare patient records relating to review performed under a non-Medicare PRO contract if authorized by those patients in accordance with State law.

(c) In accordance with its quality review responsibilities under the Act, a PRO may have access to and obtain information from, the records of non-Medicare patients who are not covered under a private review contract held by a PRO if authorized by the institution or practitioner.

§ 476.112 PRO access to records and information of intermediaries and carriers.

A PRO is authorized to have access to and require copies of Medicare records or information held by intermediaries or carriers if the PRO determines that the records or information are necessary to carry out PRO review responsibilities.

§ 476.113 PRO access to information collected for PRO purposes.

(a) Institutions and other entities must disclose to the PRO information collected by them for PRO purposes.

(b) Information collected or generated by institutions or practitioners to carry out quality review studies must be disclosed to the PRO.

§ 476.114 Limitation on data collection.

A PRO or any agent, organization, or institution acting on its behalf, that is collecting information under authority of this part, must collect only that information which is necessary to accomplish the purposes of Title XI Part B of the Act in accordance with 44 U.S.C. Chapter 35, Coordination of Federal Reporting Services Information Policy.

PRO Responsibilities

§ 476.115 Requirements for maintaining confidentiality.

(a) *Responsibilities of PRO officers and employees.* The PRO must provide reasonable physical security measures to prevent unauthorized access to PRO information and to ensure the integrity of the information, including those measures needed to secure computer files. Each PRO must instruct its officers and employees and health care institution employees participating in PRO activities of their responsibility to maintain the confidentiality of information and of the legal penalties that may be imposed for unauthorized disclosure of PRO information.

(b) *Responsible individuals within the PRO.* The PRO must assign a single individual the responsibility for maintaining the system for assuring the confidentiality of information within the PRO review system. That individual must notify HCFA of any violations of these regulations.

(c) *Training requirements.* The PRO must train participants of the PRO

review system in the proper handling of confidential information.

(d) *Authorized access.* An individual participating in the PRO review system on a routine or ongoing basis must not have authorized access to confidential PRO information unless that individual—

(1) Has completed a training program in the handling of PRO information in accordance with paragraph (c) of this section or has received comparable training from another source; and

(2) Has signed a statement indicating that he or she is aware of the legal penalties for unauthorized disclosure.

(e) *Purging of personal identifiers.* (1) the PRO must purge or arrange for purging computerized information, patient records and other noncomputerized files of all personal identifiers as soon as it is determined by HCFA that those identifiers are no longer necessary.

(2) The PRO must destroy or return to the facility from which it was collected confidential information generated from computerized information, patient records and other noncomputerized files when the PRO determines that the maintenance of hard copy is no longer necessary to serve the specific purpose for which it was obtained or generated.

(f) *Data system procedures.* The PRO must assure that organizations and consultants providing data services to the PRO have established procedures for maintaining the confidentiality of PRO information in accordance with requirements defined by the PRO and consistent with procedures established under this part.

§ 476.116 Notice to individuals and institutions under review.

The PRO must establish and implement procedures to provide patients, practitioners, and institutions under review with the following information—

(a) The title and address of the person responsible for maintenance of PRO information;

(b) The types of information that will be collected and maintained;

(c) The general rules governing disclosure of PRO information; and

(d) The procedures whereby patients, practitioners, and institutions may obtain access to information about themselves.

Disclosure of Nonconfidential Information

§ 476.120 Information subject to disclosure.

Subject to the procedures for disclosure and notice of disclosure

specified in §§ 476.104 and 476.105, the PRO must disclose (a) Nonconfidential information to any person upon request, including—

(1) The norms, criteria, and standards it uses for initial screening of cases, and for other review activities;

(2) Winning technical proposals for contracts from the Department, and winning technical proposals for subcontracts under those contracts (except for proprietary or business information);

(3) Copies of documents describing administrative procedures, agreed to between the PRO and institutions or between a PRO and the Medicare intermediary or Medicare carrier;

(4) Routine reports submitted by the PRO to HCFA to the extent that they do not contain confidential information.

(5) Summaries of the proceedings of PRO regular and other meetings of the governing body and general membership except for those portions of the summaries involving PRO deliberations, which are confidential information and subject to the provisions of § 476.139;

(6) Public information in its possession;

(7) Aggregate statistical information that does not implicitly or explicitly identify individual patients, practitioners or reviewers;

(8) Quality review study information including summaries and conclusions from which the identification of patients, practitioners and institutions has been deleted; and

(9) Information describing the characteristics of a quality review study, including a study design and methodology.

(b) Aggregate statistical information that does not implicitly or explicitly identify individual patients, practitioners or reviewers, to Federal or State health planning agencies (including Health Systems Agencies and State Health Planning and Development Agencies) in carrying out their health care planning and related activities.

§ 476.121 Optional disclosure of nonconfidential information.

A PRO may, on its own initiative, subject to the notification requirements in § 476.105, furnish the information available under § 476.120 to any person, agency, or organization.

Disclosure of Confidential Information

§ 476.130 Disclosure to the Department.

Except as limited by §§ 476.139(a) and 476.140 of this subpart, PROs must disclose all information requested by the Department to it in the manner and form required.

§ 476.131 Access to medical records for the monitoring of PROs.

HCFA or any person, organization or agency authorized by the Department or Federal statute to monitor a PRO will have access to medical records maintained by institutions or health care practitioners on Medicare patients. The monitor can require copies of the records.

§ 476.132 Disclosure of information about patients.

(a) General requirements for disclosure.

Except as specified in paragraph (b) of this section, a PRO must—

(1) Disclose patient identified information in its possession to the identified patient or the patient's representative if—

(i) The patient or the patient's representative requests the information in writing;

(ii) The request by a patient's representative includes the designation, by the patient, of the representative; and

(iii) All other patients and practitioner identifiers have been removed.

(2) Seek the advice of the attending practitioner that treated the patient regarding the appropriateness of direct disclosure to the patient 15 days before the PRO provides the requested information. If the attending practitioner states that the released information could harm the patient, the PRO must act in accordance with paragraph (c)(2) of this section. The PRO must make disclosure to the patient or patient's representative within 30 calendar days of receipt of the request.

(b) *Exceptions.* (1) If the request is in connection with an initial denial determination under section 1154(a)(3) of the Act, the PRO—

(i) Need not seek the advice of the practitioner that treated the patient regarding the appropriateness of direct disclosure to the patient; and

(ii) Must provide only the information used to support that determination in accordance with the procedures for disclosure of information relating to determinations under § 473.28.

(2) A PRO must disclose information regarding PRO deliberation only as specified in § 476.139(a).

(3) A PRO must disclose quality review study information only as specified in § 476.140.

(c) *Manner of disclosure.* (1) The PRO must disclose the patient information directly to the patient unless knowledge of the information could harm the patient.

(2) If knowledge of the information could harm the patient, the PRO must

disclose the information to the patient's designated representative.

(3) If the patient is mentally, physically or legally unable to designate a representative, the PRO must disclose the information to a person whom the PRO determines is responsible for the patient.

The PRO must first attempt to make that determination based on the medical record. If the responsible person is not named in the medical record, then the PRO may rely on the attending practitioner for the information. If the practitioner is unable to provide a name, then the PRO must make a determination based on other reliable information.

§ 476.133 Disclosure of information about practitioners, reviewers and institutions.

(a) *General requirements for disclosure.* Except as specified in paragraph (b) of this section, the following provisions are required of the PRO.

(1) *Disclosure to the identified individual or institution.* A PRO must disclose, to particular practitioners, reviewers and institutions, information about themselves, upon request, and may disclose it to them without a request.

(2) *Disclosure to others.* (i) A PRO must disclose to an institution, upon request, information on a practitioner to the extent that the information displays practice or performance patterns of the practitioner in that institution.

(ii) A PRO must disclose to Federal and State agencies that are responsible for the investigation of fraud and abuse of the Medicare program and for licensing and certification, upon request, information that displays practice or performance patterns of a practitioner or institution, in accordance with the procedures for disclosure specified in §§ 476.137 and 476.138.

(iii) A PRO may disclose to any person, agency or organization, information on a particular practitioner or reviewer with the consent of that practitioner or reviewer provided that the information does not identify other individuals.

(b) *Exceptions.* (1) If the request is in connection with an initial denial determination or a change resulting from a diagnostic related group (DRG) coding validation under Part 466 of this subchapter, the PRO must provide only the information used to support that determination in accordance with the procedures for disclosure of information relating to determinations under § 473.24.

(2) A PRO must disclose information regarding PRO deliberations only as specified in § 476.139(a).

(3) A PRO must disclose quality review study information only as specified in § 476.140.

§ 476.134 Verification and amendment of PRO information.

(a) A PRO must verify the accuracy of its information concerning patients, practitioners, reviewers, and institutions and must permit the individual or institution to request an amendment of pertinent information that is in the possession of the PRO.

(b) If the PRO agrees with the request for amendment, the PRO must correct the information in its possession. If the information being amended has already been disclosed, the PRO must forward the amended information to the requester where it may affect decisions about a particular provider, practitioner or case under review.

(c) If the PRO disagrees with the request for amendment, a notation of the request reasons for the request, and the reasons for refusal must be included with the information and attached to any disclosure of the information.

§ 476.135 Disclosure necessary to perform review responsibilities.

(a) *Disclosure to conduct review.* The PRO must disclose or arrange for disclosure of information to individuals and institutions within the PRO review system as necessary to fulfill their particular duties and functions under Title XI Part B of the Act.

(b) *Disclosure to consultants and subcontractors.* The PRO must disclose to consultants or subcontractors the information they need to provide specified services to the PRO.

(c) *Disclosure to other PRO and medical review boards.* The PRO must disclose—

- (1) To another PRO, information on patients and practitioners who are subject to review by the other PRO; and
- (2) To medical review boards established under section 1881 of the Act, confidential information on patients, practitioners and institutions receiving or furnishing end stage renal disease services.

§ 476.136 Disclosure to intermediaries and carriers.

(a) *Required disclosure.* Except as specified in §§ 476.139(a) and 476.140 relating to disclosure of PRO deliberations and quality review study information, a PRO must disclose to intermediaries and carriers PRO information that relates to, or is necessary for, payment of claims for Medicare as follows:

(1) Review determinations and claims forms for health care services, furnished in the manner and form agreed to by the PRO and the intermediary or carrier.

(2) Upon request, copies of medical records acquired from practitioners or institutions for review purposes.

(3) PRO information about a particular patient or practitioner if the PRO and the intermediary or carrier (or HCFA if the PRO and the intermediary or carrier cannot agree) determine that the information is necessary for the administration of the Medicare program.

(b) *Optional disclosure.* The PRO may disclose the information specified in paragraph (a) of this section to intermediaries and carriers without a request.

§ 476.137 Disclosure to Federal and State enforcement agencies responsible for the investigation or identification of fraud or abuse of the Medicare program.

(a) *Required disclosure.* Except as specified in §§ 476.139(a) and 476.140 relating to disclosure of PRO deliberations and quality review study information, the PRO must disclose confidential information relevant to an investigation of fraud or abuse of the Medicare program, including PRO medical necessity determinations and other information that includes patterns of the practice or performance of a practitioner or institution, when a written request is received from a State or Federal enforcement agency responsible for the investigation or identification of fraud or abuse of the Medicare program that—

- (1) Identifies the name and title of the individual initiating the request,
- (2) Identifies the physician or institution about which information is requested, and
- (3) States affirmatively that the institution or practitioner is currently under investigation for fraud or abuse of the Medicare program and that the information is needed in furtherance of that investigation.

(b) *Optional disclosure.* The PRO may provide the information specified in paragraph (a) of this section to Federal or State fraud and abuse enforcement agencies responsible for the investigation or identification of fraud or abuse of the Medicare program, without a request.

(c) *Optional disclosure.* The PRO may provide the information specified in paragraph (a) of this section to Federal or State fraud and abuse enforcement agencies responsible for the investigation or identification of fraud or abuse of the Medicare program, without a request.

§ 476.138 Disclosure for other specified purposes.

(a) *General requirements for disclosure.* Except as specified in paragraph (b) of this section, the following provisions are required of the PRO.

(1) *Disclosure to licensing and certification bodies.* (i) A PRO must disclose confidential information upon request, to State or Federal licensing bodies responsible for the professional licensure of a practitioner or a particular institution. Confidential information, including PRO medical necessity determinations that display the practice or performance patterns of that practitioner, must be disclosed by the PRO but only to the extent that it is required by the agency to carry out a function within the jurisdiction of the agency under Federal or State law.

(ii) A PRO may provide the information specified in paragraph (a)(1)(i) of this section to the State or Federal licensing body without request.

(2) *Disclosure to State and local public health officials.* A PRO must disclose PRO information to State and local public health officials whenever the PRO determines that the disclosure of the information is necessary to protect against a substantial risk to the public health.

(3) *Disclosure to the courts.* Patient identified records in the possession of a PRO, are not subject to subpoena or discovery in a civil action, including an administrative, judicial or arbitration proceeding.

(b) *Exceptions.* (1) The restriction set forth in paragraph (a)(3) of this section does not apply to HHS, including Inspector General, administrative subpoenas issued in the course of audits and investigations of Department programs, in the course of administrative hearings held under the Social Security Act or to disclosures to the General Accounting Office as necessary to carry out its statutory responsibilities.

(2) A PRO must disclose information regarding PRO deliberations and quality review study information only as specified in §§ 476.139(a) and 476.140.

§ 476.139 Disclosure of PRO deliberations and decisions.

(a) *PRO deliberations.* (1) A PRO must not disclose its deliberations except to—

(i) HCFA, at the PRO office or at a subcontracted organization;

(ii) HCFA, to the extent that the deliberations are incorporated in sanction and appeals reports; or

(iii) The Office of the Inspector General, and the General Accounting Office as necessary to carry out statutory responsibilities.

(2) PRO deliberations are not disclosable, either in written form or through oral testimony, in connection with the administrative hearing or review of a beneficiary's claim.

(b) *Reasons for PRO decisions.* (1) A PRO may disclose to those who have access to PRO information under other provisions of this subpart, the reasons for PRO decisions pertaining to that information provided that the opinions or judgments of a particular individual or practitioner cannot be identified.

(2) A PRO must disclose, if requested in connection with the administrative hearing or review of a beneficiary's claim, the reasons for PRO decisions. The PRO must include the detailed facts, findings and conclusions supporting the PRO's determination. The PRO must insure that the opinions or judgments of a particular individual or practitioner cannot be identified through the materials that are disclosed.

§ 476.140 Disclosure of quality review study information.

(a) A PRO must disclose, onsite, quality review study information with identifiers of patients, practitioners or institutions to—

(1) Representatives of authorized licensure, accreditation or certification agencies as is required by the agencies in carrying out functions which are within the jurisdiction of such agencies under state law; to federal and state agencies responsible for identifying risks to the public health when there is substantial risk to the public health; HCFA; or to Federal and State fraud and abuse enforcement agencies;

(2) An institution or practitioner, if the information is limited to health care services furnished by the institution or practitioner; and

(3) A medical review board established under section 1881 of the Act pertaining to end-stage renal disease facilities, if the information is limited to health care services subject to its review.

(b) A PRO must disclose quality review study information with identifiers of patients, practitioners or institutions to the Office of the Inspector General and the General Accounting Office as necessary to carry out statutory responsibilities.

(c) A PRO may disclose information offsite from a particular quality review study to any institution or practitioner involved in that study, provided the disclosed information is limited to that institution or practitioner.

(d) An institution or group of practitioners may redisclose quality review study information, if the information is limited to health care services they provided.

(e) Quality review study information with patient identifiers is not subject to subpoena or discovery in a civil action, including an administrative, judicial or

arbitration proceeding. This restriction does not apply to HHS, including Inspector General, administrative subpoenas issued in the course of audits and investigations of Department programs, in the course of administrative hearings held under the Social Security Act, or to disclosures to the General Accounting Office as necessary to carry out its statutory responsibilities.

§ 476.141 Disclosure of PRO interpretations on the quality of health care.

Subject to the procedures for disclosure and notice of disclosure specified in §§ 476.104 and 476.105, a PRO may disclose to the public PRO interpretations and generalizations on the quality of health care that identify a particular institution.

§ 476.142 Disclosure of sanction reports.

(a) The PRO must disclose sanction reports directly to the Office of the Inspector General and, if requested, to HCFA.

(b) The PRO must upon request, and may without a request, disclose sanction reports to State and Federal agencies responsible for the identification, investigation or prosecution of cases of fraud or abuse in accordance with § 476.137.

(c) HCFA will disclose sanction determinations in accordance with Part 474 of this chapter.

§ 476.143 PRO involvement in shared health data systems.

(a) *Information collected by a PRO.* Except as prohibited in paragraph (b) of this section, information collected by a PRO may be processed and stored by a cooperative health statistics system established under the Public Health Service Act (42 U.S.C. 242k) or other State or Federally authorized shared data system.

(b) *PRO participation.* A PRO may not participate in a cooperative health statistics system or other shared health data system if the disclosure rules of the system would prevent the PRO from complying with the rules of this part.

(c) *Disclosure of PRO information obtained by a shared health data system.* PRO information must not be disclosed by the shared health data system unless—

(1) The source from which the PRO acquired the information consents to or requests disclosure; or

(2) The PRO requests the disclosure of the information to carry out a disclosure permitted under a provision of this part.

(Catalog of Federal Domestic Assistance Program Nos. 13.773 Medicare—Hospital

Insurance; 13.774 Medicare—Supplementary Medical Insurance)

Dated: December 17, 1984.

Carolyn K. Davis,
Administrator, Health Care Financing Administration.

Approved: January 28, 1985.

Margaret M. Heckler,
Secretary.

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42 CFR Part 473

[HSQ-111-F]

Medicare Program; Utilization and Quality Control Peer Review Organization (PRO) Reconsiderations and Appeals

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: These regulations implement that portion of the Peer Review Improvement Act of 1982 that provides for reconsiderations and appeals of Utilization and Quality Control Peer Review Organization (PRO) initial determinations. We are establishing procedures for a PRO to reconsider both its initial denial determinations regarding the medical necessity, reasonableness and appropriateness of health care services furnished or proposed to be furnished to a Medicare beneficiary in a health care institution and the application of the limitation of liability provision. We are also including in this final rule procedures for administrative appeals to the Department following a PRO reconsidered determination and judicial review following administrative appeals.

In addition, these regulations establish procedures for review of a PRO change in the diagnostic and procedural coding information that results in assignment of a discharge to a different diagnosis related group (DRG). This pertains to the review of claims for services furnished in hospitals reimbursed by Medicare under the prospective payment system.

EFFECTIVE DATE: May 17, 1985. Sections 473.18, 473.34 473.36 and 473.42 of this rule contain information collection requirements with which the public is not required to comply until the Executive Office of Management and Budget (EOMB) approves these requirements. (See section V. of this preamble for a discussion of information collection.)

FOR FURTHER INFORMATION CONTACT:

Mary Kay Terry, (301) 594-7910.

SUPPLEMENTARY INFORMATION:**1. Background**

The Peer Review Improvement Act of 1982 (Title I, Subtitle C of the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982, Pub. L. 97-248) amended Part B of Title XI of the Social Security Act (the Act) to establish the Utilization and Quality Control Peer Review Organization (PRO) program. This program, when fully implemented, will replace the existing Professional Standards Review Organization (PSRO) program. Initially, PROs have assumed responsibility for the review of hospital inpatient health care services for which payment may be made by Medicare. A PRO determines whether those services are reasonable and medically necessary, are of a quality that meets professionally recognized standards, and whether services and items provided on an inpatient basis could be effectively provided more economically on an outpatient basis or in a different type of inpatient facility.

Title VI of the Social Security Amendments of 1983, Pub. L. 98-21, added another review function. Under the new section 1866(d) of the Act, Medicare payment for hospital inpatient operating costs is based on a fixed amount, determined in advance for each case, according to a diagnosis-related code (DRG), which will be assigned to a case. Section 1866(a)(1)(F) of the Act requires PRO review of the validity of the diagnostic and procedural information supplied by the hospital and used by the intermediary to assign the DRG.

On July 17, 1984, we published a notice of proposed rulemaking (NPRM) (49 FR 29041) concerning reconsiderations and appeals of PRO determinations under section 1155 of the Act, which was added by the Peer Review Improvement of 1982. The proposal elicited 47 letters from the public. The provisions of the NPRM, the comments received and the changes in response to those comments, as well as additional changes made for clarity, are discussed below. Additional details of our proposal and the rationale for the proposed policies are contained in the preamble to the NPRM.

It should be noted that the provisions of this final rule may be revised later to bring them into conformance with planned amendments to the rules implementing section 1879 of the Act, which concerns the limitation on liability when Medicare claims are disallowed because the services or

items were excluded from coverage as not medically reasonable and necessary or as custodial care. Proposed amendments are being developed and will be published for comment.

II. Provisions of the Proposed Rule

In the July 17, 1984 NPRM, we proposed that a party to an initial PRO determination who is dissatisfied with the determination is entitled to a PRO reconsideration of whether the services that were furnished (or proposed to be furnished)—

- Are medically necessary and reasonable, given the diagnosis and circumstances under which they were or would be furnished; and
- Were furnished in an appropriate setting.

If a PRO has determined that liability will not be waived under section 1879 of the Act for a noncovered furnished service, only the provider, practitioners or beneficiary who is liable would be entitled to a reconsideration of the determination. In addition, when it is established that the beneficiary (who is liable) is not pursuing his or her appeal rights, a provider or practitioner would be entitled to a reconsideration under section 1879 of the Act.

We proposed procedures and time limits for—

- Submitting reconsideration requests;
- Providing the parties with an opportunity to review all medical information upon which the initial determination was based and to submit additional information to be considered by the PRO in making its reconsidered determination; and
- Making the reconsidered determination and notifying the parties.

In addition, we proposed qualifications for organizations and individuals who perform the reconsideration of an initial determination so that the reconsideration would be fair.

We also proposed to use the current Part A procedures under 42 CFR Part 405, Subpart G for administrative appeals and judicial review. However, some modifications were made to reflect the fact that under section 1155 of the Act the amount in controversy necessary for a beneficiary to receive a hearing is \$200 and \$2,000 for a judicial review. However, these amounts do not apply to hearings under section 1879 of the Act, for which the amount in controversy is \$100 for a hearing and (for Part A only) \$1,000 for a judicial review. (There is no judicial review of determinations of Part B claims under section 1879 of the Act.)

III. Analysis and Response to Comments

We received 47 letters from individuals and organizations. These commenters included hospitals, associations representing hospitals, a State agency concerned with the elderly, an association representing the elderly, two legal advocates for the elderly, organizations representing physicians, an organization representing nurses, an organization representing medical colleges, professional standards review organizations (PSROs), an organization representing PSROs, and two Medicare fiscal intermediaries. The main issues in the letters that we received and our responses to them are discussed below.

A. HCFA Should Prepare Special Information for the Beneficiary That Explains Reconsideration and Appeals

Comment: Two commenters think that a beneficiary will have difficulty in understanding the reconsideration and appeals process. Therefore, the commenters urge HCFA to prepare a brochure that describes the reconsideration and appeals process for a beneficiary to receive at the time of a hospital admission.

Response: We believe that it is of utmost importance that beneficiaries be fully informed of the PRO review process, especially PRO determinations that affect payment. We agree that a beneficiary should receive a description of the reconsideration and appeals process, but believe that the best time for receipt of this information will be at the time of receipt of the initial denial notice. Therefore, under § 466.94 (contained in another final rule published in this issue of the **Federal Register**, Utilization and Quality Control Peer Review Organization (PRO): Assumption of Responsibilities and Medicare Review Functions and Coordination of Medicaid with Peer Review Organization (PRO Review)), we are requiring that a PRO include this information in the beneficiary's initial denial notice. The denial notice must include a statement informing each party or the party's representative—

- (1) Of the right to reconsideration;
- (2) When and how to request a reconsideration; and
- (3) The locations for filing the request.

Information regarding hearings will be supplied with notices of reconsidered determinations.

Also, hospitals are not precluded from making this information available at the time of a beneficiary's admission.

B. PRO Review of Changes in Procedural or Diagnostic Information That Result in a DRG Change

Comment: One commenter requested clarification of the proposed § 473.18(d), which lets the PRO decide whether to review its changes to diagnostic and procedural coding supplied by the hospital that resulted in a DRG change based upon DRG validation.

Response: We agree that this was unclear and have modified proposed § 473.18(d) (now § 473.15). At the request of a provider or a practitioner, the PRO will review a DRG change resulting from a DRG validation that changed the diagnostic or procedural information and caused lower payment. This review by the PRO is under section 1866(a)(1)(F) of the Act, and that section does not provide for further review; that is, the review of the DRG coding change is final and is not subject to a further hearing.

C. Provide for Reconsideration and Appeal of Denial of Grace Days

Comment: Several commenters believe that denial of grace days should be appealable because they may affect the health care of beneficiaries if not enough time is allowed for post-discharge arrangements. In contrast, another commenter said that the final rule should state that the PRO decision regarding the number of grace days available to a beneficiary is not subject to a reconsideration.

Response: The granting of grace days is purely discretionary and not an initial denial determination that would be subject to a reconsideration. Section 1154(a)(2) of the Act specifies that PROs are to make initial determinations based upon review described at sections 1154(a)(1)(A) and 1154(a)(1)(C) of the Act. Initial determinations under section 1154(a)(1)(A) of the Act involve the issue of whether the services were reasonable and medically necessary or constituted custodial care. Section 1154(a)(1)(C) of the Act involves the issue of whether services proposed to be furnished would be delivered in the most appropriate setting.

Under section 1154(a)(2) of the Act, these determinations are conclusive for Medicare payment purposes, with four exceptions. One of these exceptions is that a PRO may extend payment for not more than two days when it finds that post-discharge planning is necessary and that the provider did not know that payment for these days would not otherwise be made (section 1154(a)(2)(B) of the Act.) This PRO function is therefore different from the determinations based on sections

1154(a)(1)(A) and 1154(a)(1)(C) of the Act because, when a PRO allows "grace days" under section 1154(a)(2)(B) of the Act, it does not do so based on medical necessity, reasonableness, or appropriateness of the care in question. Further, section 1154(a)(2)(C) of the Act makes clear that only a determination under sections 1154(a)(1)(A) or (C) is subject to the hearing provisions in section 1155. Section 1154(a)(2)(C) of the Act applies to "such determination", clearly referring only to the determinations made under sections 1154(a)(1)(A) or (C) of the Act. The awarding of "grace days" under section 1154(a)(2)(B) of the Act is not a determination under section 1154(a)(1)(A) or (C). Section 1154(a)(2)(C) of the Act thus clearly contemplates that the awarding of "grace days" was not the type of PRO activity that was intended to be subject to the hearing and review provisions in section 1155 of the Act.

We agree that this final rule should state that the granting of grace days is not subject to reconsideration, and § 473.14(c)(1) contains this information.

D. No Reconsideration or Appeal Should be Allowed if There are no Direct Medicare Payment Issues in Dispute

1. Comment: One commenter wants our final rule to continue the current procedures that allow the beneficiary to pursue an appeal based on the coverage issues even if payment is made under the limitation of liability provisions in section 1879 of the Act because no supplemental insurance policy will pay the portion not covered by Medicare if the PRO has issued a denial involving medical necessity. Another commenter questions whether Congress intended, in providing in section 1155 of the Act for a reconsideration, that a party merely be "dissatisfied" with a PRO denial even if there are no payment consequences to that party.

Response: We agree with the first comment. We will continue to allow a beneficiary to obtain a reconsideration or hearing of a coverage issue in dispute even if we have paid for the denied service under the limitation of liability provisions of section 1879 of the Act.

With regard to the second comment, any party, including providers, practitioners, or beneficiaries who are dissatisfied with an initial denial determination, has access to a PRO reconsideration. However, section 1155 of the Act further provides for a hearing only for the beneficiary, and only when the reconsideration is adverse to the beneficiary. As noted above in the first comment, a determination of noncoverage on grounds that medical

necessity was lacking may be adverse even if we make payment for the noncovered services under section 1879 of the Act. A determination of that kind may also preclude future payments under section 1879 of the Act for a similar service, since the beneficiary is on notice of the noncoverage.

2. Comment: In addition, some commenters believe that providers or practitioners should be given the right to a reconsideration even if they are not liable for payment under the limitation of liability provision.

Response: We agree with this comment. Section 473.16 governs reconsideration rights under the PRO program, not the limitation of liability provisions. Therefore, providers or practitioners may obtain a reconsideration on the issues of medical necessity, reasonableness of care, and appropriateness of the setting.

E. PRO Criteria

Comment: One commenter suggested that practitioners be allowed to appeal the PRO criteria and review process that the practitioner considers to be unreasonable and detrimental to patient care or which may affect the general public interest.

Response: We believe that PRO criteria should be developed with local peer participation to assure that they are reasonable or not detrimental. Section 1154(a)(6) of the Act requires that a PRO develop professionally developed norms of care, diagnosis and treatment criteria (as defined in Part 466) based on local patterns of medical practice. Such criteria are developed by physician members of the PRO. We believe that this is the appropriate process for raising questions concerning PRO criteria. These criteria are used by a PRO for the purpose of screening cases for possible unnecessary, unreasonable or inappropriate care.

If any questionable case is identified using these criteria, a peer physician or surgeon associated with the PRO will contact or attempt to contact the physician to discuss the case further. A denial may be issued only after this discussion or attempt and only if the peer physician concludes that the proposed procedure is not reasonable or medically necessary, or could, with adequate safety, be provided on an outpatient basis.

F. Justification for Reconsideration Requests

Comment: Three PSROs recommend that a provider or practitioner be required to supply a detailed justification with each reconsideration

request to prevent a frivolous request that may result in unnecessarily burdening a PRO staff and causing excessive delay in completing other reconsiderations.

Response: Under section 1155 of the Act, a beneficiary, provider, or practitioner who is dissatisfied with a PRO determination is entitled to a reconsideration by the PRO that made the initial determination.

To afford a practitioner and a provider adequate opportunity for this statutorily required reconsideration, we believe that a provider or practitioner should be required only to submit the request for reconsideration timely and in writing. Any additional restrictions would be inconsistent with the intention of the statute. However, the PRO will reconsider its determination based on the record, which includes the same record on which the initial determination was based and additional information submitted along with a reconsideration request.

G. Where to File a Request for Reconsideration

Comment: Several commenters object to the proposed § 473.20(a)(2), which allows a beneficiary to file a request for a reconsideration with a PRO representative at a hospital. The commenters believe that, because these representatives will be present only a few days each month, the hospital will be burdened with the costs of handling the requests. Another commenter recommends that a provider and practitioner be allowed to use the same filing locations as a beneficiary.

Response: We agree that the proposed provision that allows a beneficiary to file a request for a reconsideration with a PRO representative at the hospital may place an unreasonable burden on the hospital. Therefore, we are revising that section (now § 473.18) and omitting that provision from the final rule. However, we are retaining the other locations available to a beneficiary for filing for a reconsideration.

With regard to the second comment, it is appropriate that beneficiaries, because of their relative lack of familiarity with the health care system as compared with practitioners and providers, be given the broadest opportunity to initiate a reconsideration; whereas practitioners and providers are thoroughly familiar with requesting reconsiderations and should have no problem in making a request to the PRO or its subcontractor who made the initial determination.

H. Time Period for Request of Review of Preadmission Denial

Comment: One commenter suggested that the proposed § 473.28(b) (now § 473.20) be revised to allow a party more than three days to request a reconsideration for a preadmission denial. This commenter believes that three days is not enough time to permit the provider, practitioner and beneficiary to file a request and prepare documentation that would be sufficient to support a reconsideration.

Response: This three day rule for requesting a reconsideration is to obtain expedited PRO reconsideration. It does not replace a party's right to request a reconsideration within the usual 60 day time period. We have clarified that the three day time period applies to receiving an expedited reconsideration. The short timeframe is necessary to avoid delay in obtaining proper hospital treatment if the initial denial determination is reversed and the admission is found to be necessary. Therefore, a late request for an expedited reconsideration will not be granted. If a party so wishes, it may take up to 60 days to request a reconsideration. However, we note that the filing date and reconsideration date are not necessarily the same. In most cases, we expect that the reconsideration will not be held until the third day after the request is received by the PRO. This time is available to a claimant to prepare and submit additional documentation.

I. Provider and Attending Practitioner Notification When Beneficiary Requests a Reconsideration

Comment: One commenter recommends that we require the PRO to notify the provider and attending practitioner whenever a beneficiary requests a reconsideration.

Response: We assume that the commenter recommended this notification to allow the provider the opportunity to represent the beneficiary. Because the provider cannot represent the beneficiary in a reconsideration, this additional notification would serve no purpose. (See response to comment U of this section: Provider representation of beneficiary). The provider and practitioner are notified of the reconsidered determination. Therefore, we will not make this requested change.

J. Proving That a Beneficiary Will Not Seek Reconsideration of an Initial Determination

1. Comment: Two commenters think that we should establish specific criteria to explain how the provider or

practitioner can establish that a beneficiary who is liable is not going to pursue his or her right to a reconsideration of the initial determination. In addition, some commenters believe that a provider or practitioner should be given the right to a reconsideration even if it is not liable for payment due to the limitation of liability provision in section 1879 of the Act.

Response: These comments reflect some confusion. In § 473.18(a) of the NPRM (now § 473.16(a)), we clearly stated that a provider or practitioner has a right to reconsideration of a PRO determination as to reasonableness, medical necessity, and appropriateness. This is not dependent on whether the beneficiary also asks for reconsideration. Section 473.16(a) repeats this provision (although it has been redrafted for clarity). The commenters were probably reacting to § 473.18(c) of the NPRM, which described appeal rights not under section 1155 of the Act (the PRO statute), but rather under the limitation of liability provisions in section 1879(d) of the Act. That provision clearly states that a provider or practitioner may appeal a determination under section 1879 of the Act only after we determine that the beneficiary will not exercise his or her appeal rights. We cannot change this statutory limitation. However, to clarify the regulation, we are removing most of the references to section 1879 procedures from Subpart B of 42 CFR Part 473. Instead, in § 473.14(c), we refer the reader to the regulations containing the procedures for appealing Medicare determinations made by HCFA and its fiscal intermediaries and carriers, including those under section 1879 of the Act.

K. PRO Release of Medical Records

Comment: Thirteen commenters recommended that the proposed § 473.32 (now § 473.24) be revised to prohibit the PRO from releasing to the beneficiary the material upon which the initial determination was based. They stated that it is inappropriate for the PRO to release the patient's medical record without the provider's consent.

Response: This final rule addresses PRO information used in reaching a decision and the need of individuals to verify that that information is correct.

However, we recognize that there must be safeguards to which PROs must adhere to assure that certain sensitive patient information will not be released. We plan to publish those rules in a future issue of the *Federal Register*. They will be located in Part 476 of this

chapter, which contains the Department's rules concerning Acquisition, Disclosure, and Protection of PRO information. Once information is in possession of a PRO, it belongs to that PRO and it would be inappropriate to require that a PRO obtain approval before releasing its own information to a beneficiary. We have clarified the proposed § 473.32 (now § 473.24(a)) and § 476.132(b)(1) to require a PRO to provide the beneficiary only with the information that was used to support the initial denial determination.

L. Identify PRO Reviewers and Make Public PRO Deliberations

Comment: Several commenters stated that PROs should furnish the identity of reviewers and the record of the initial determination deliberation to the parties to aid in their understanding and appeal of an adverse determination.

Response: As stated earlier, parties to a reconsideration should be given the information that formed the basis of the determination. The PRO will release information about the facts and reasons supporting its decision so that the parties will be fully informed about the determination. Also, we agree that the identity of a reviewer can be released if the reviewer agrees. However, we are prohibiting a PRO from releasing the record of the PRO deliberations because we believe that release of this information would inhibit frank and thorough discussion among the reviewers.

M. Charges for PRO Photocopying

Comment: Five commenters object to the requirement that a provider is not allowed to charge a PRO for photocopying of information that is submitted to a PRO for a reconsideration and is not reimbursed by HCFA for such costs.

Response: We believe it is important that PROs have adequate access to medical records to enable them to carry out required activities. This includes the right to request and receive copies as they deem necessary including preadmission test records. In some cases, this will mean that the PRO will request hospitals to photocopy specific medical records and mail them to the PRO.

The prospective payment rates are computed according to the provisions of the law and are also based on the best available data at the time of computation. Administrative costs are included in the Federal and hospital specific portions of prospective payments by virtue of their being incurred and reported by hospitals for the years that represent the data bases

for the prospective payment system. These bases include all allowable administrative costs of a hospital, including many that are not specifically incurred for Medicare purposes.

Prior to the use of PROs, review of inpatient hospital services was carried out either at the hospital or offsite. Offsite review sometimes required that the hospital mail patient records to Medicare fiscal intermediaries. These costs were subsumed in the hospital's administrative costs that in turn were reflected in Medicare cost reimbursement calculations. Costs related to such activities are accounted for, in some measure, in the prospective payment base rates.

We also believe that the fiscal benefits of PRO review will compensate for any possible increased costs. For example, in many cases, PROs' preadmission review activities will protect hospitals from retrospective denials. Thus, there will be trade-offs between a hospital's cost of providing medical records to PROs and PRO's performance of review that may assist hospitals in avoiding unnecessary expenditures.

N. Incentive for PRO To Affirm Its Initial Determination

Comment: Two commenters feel that due process will be compromised because a PRO has a strong incentive to affirm the initial determination during the reconsideration process because the PRO contract has specified targets and because we would allow the individual who makes the initial determination to also reconsider that determination.

Response: PRO objectives are targets for reducing unnecessary or inappropriate care, not rigid quotas. While PROs have negotiated specific contract objectives, we recognize that there are circumstances under which the objectives may need to be modified. For example, quality objectives would be modified if data developed during the course of the contract demonstrate that the problem targeted is more severe than previously thought, or if the PRO identifies a different problem of greater importance. Utilization objectives would be modified for demographic shifts (for example, an influx of Medicare beneficiaries into the PRO service area), for the effects of new technology, etc.

We agree with the second part of the comment that the individual who makes the reconsidered determination should not be the individual who made the initial denial determination. Therefore, we have revised the proposed § 473.24 (now § 473.28), Qualifications of a reconsideration reviewer, accordingly.

O. Who Should Make the Reconsidered Determination

1. Comment: One commenter wants to know the circumstances in which we would allow a physician to reconsider an initial denial determination involving services provided by a dentist.

Response: We believe it is the intent of the statute that the most effective method of peer review is for doctors of medicine to review doctors of medicine, doctors of osteopathy to review doctors of osteopathy, and doctors of dentistry to review doctors of dentistry. We have, however, made an exception to this rule in § 466.98 (published in another final rule elsewhere in this issue of the Federal Register), in situations where a PRO determines that peer practitioners are not available to perform peer review effectively. For example, if there is a shortage of peers which hinders adequate and timely review, a doctor of medicine or doctor of osteopathy may make initial denial determinations involving services provided by a doctor of medicine, doctor of osteopathy, or doctor of dentistry.

2. Comment: Several commenters believe that we should require that the reconsideration reviewer be a specialist in the type of services under review. Furthermore, commenters believe that the individual who reviews the change in DRG coding should have experience and proficiency in ICD-9-CM coding and DRG assignment.

Response: We agree that a reconsideration reviewer should be a specialist in the type of services under review except where meeting this requirement would compromise the effectiveness or efficiency of PRO review. For example, if the only specialist available to reconsider a case is located at the opposite side of the state, we would not require that the specialist travel an excessive distance to hold the reconsideration or for the party to travel an excessive distance to reach the reconsideration reviewer.

We also agree that the individual who reviews changes in DRG coding must be qualified through training and experience to review ICD-9-CM coding. In addition, we are providing that the individual who reviews changes in DRG procedural or diagnostic information must be a physician. These provisions are located in the regulations at § 473.15.

Q. Scope of Information To Be Considered During Reconsideration

Comment: Three commenters believe that proposed § 473.34, Evidence to be considered by the reconsideration reviewer, is too restrictive and should

be revised to allow oral testimony by the parties, declarations from medical witnesses and submission of rebuttal evidence upon completion of the initial presentation to the reconsideration reviewer. In addition, one commenter suggests that if we decide to prohibit a reconsideration hearing, we should not limit the scope of written evidentiary materials that may be submitted, as long as they pertain to the issues under review.

Response: Nothing in the proposed § 473.34 (now § 473.30) restricts the types of additional evidence that may be submitted by a party. We believe that the use of "additional evidence submitted by a party" as contained in § 473.30 is very broad and permits the PRO to consider declarations from medical witnesses and submission of rebuttal evidence. However, the types of issues raised do not generally lend themselves to oral testimony; rather they lend themselves to a review of documentation. Should a PRO choose to accept oral testimony, we will spell out procedures the PRO must follow in accepting such testimony in the PRO administrative guidelines. We anticipate, however, that the need for oral evidence should be rare. Therefore, we are making no substantive changes to § 473.30 of this final rule.

R. Timely Completion of Reconsidered Determination

Comment: Eighteen commenters suggested that proposed § 473.42(b) (now § 473.32(b)) require that a reconsideration requested by a provider or practitioner be performed in a timely manner; that is, within 30 days of the receipt of the reconsideration request. The commenters are concerned that payment decisions for providers and practitioners may be deferred indefinitely.

Response: We agree, and § 473.32 provides that a PRO must complete its reconsideration and send written notice within 30 working days after receipt of a request for reconsideration from a provider or practitioner.

S. Issue Notice of Reconsidered Determination Within a Specific Time Period

Comment: Two commenters suggest that rather than requiring the PRO to provide "prompt" written notice of its reconsidered determination to the intermediary or carrier, as appropriate (proposed § 473.44(b)), we should require that this notice be issued within a specific time period.

Response: We agree; therefore, we are revising proposed § 473.44(b) (now § 473.34(b)) to require that the PRO

provide written notification of its reconsidered determination to the intermediary or carrier, as appropriate, within 30 days of the determination. We are also requiring that the PRO make this notification of the reconsidered determination only if the initial denial determination is modified or reversed.

T. Access to Record of PRO Reconsidered Determination

Comment: One commenter thinks that the proposed rule does not adequately explain who has access to the record of a PRO reconsideration.

Response: As indicated in the proposed rule, section 1160 of the Act sets forth the statutory rules that govern access and disclosure of the record of a PRO reconsideration. As noted earlier, we plan to publish the final rule implementing that section, Acquisition, Protection, and Disclosure of Utilization and Quality Control Peer Review Organization (PRO) Information in a future issue of the Federal Register. The regulations will be placed in Part 476 of this chapter.

U. Provider Representation of Beneficiary

Comment: Ten commenters believe that providers should be allowed to represent beneficiaries in hearings regarding medical necessity issues.

Response: We are not accepting this suggestion. We believe that it would be inappropriate to permit a provider to represent a beneficiary in appealing claims under Medicare because, under section 1879 of the Act, liability for the Medicare claim may be assigned to the beneficiary, physician, or other attending practitioner that furnished the service. Therefore, allowing a provider to represent a beneficiary whose claim has been denied could result in a conflict of interest. As to PRO appeals, section 1155 of the Act was clearly designed to permit hearings only for beneficiaries and not for providers, physicians, and other practitioners. Allowing a provider to represent a beneficiary would permit an alternative avenue of provider appeal rights clearly not authorized under section 1155 or 1879 of the Act and not in accordance with Congressional intent. We have not addressed this issue in the regulations text, because we will continue current Medicare policy, as provided in section 3789C of the Part A Intermediary Manual (page 3-262.14, revision 1079). Extant Medicare policy is that a provider may not represent a beneficiary in appealing claims denied under Part A of Medicare.

V. Time Period for Beneficiary to Request a Hearing

Comment: Two commenters believe that there should be a time limit on how long the beneficiary has to decide not to request a hearing in order that a provider or practitioner be able to file timely, if the liability of the beneficiary is at issue.

Response: Under § 473.42(b) (proposed at § 473.28), the beneficiary has 60 days from receipt of the notice of the PRO reconsidered determination to request a hearing.

Providers and practitioners may protect their right to a administrative hearing under section 1879 of the Act by submitting their request during this same 60 day period.

W. Hearing Issues for a Provider and Practitioner

Comment: Twenty-three commenters stated that proposed § 473.50(c) should not limit a provider and practitioner to a hearing based only on the issues of knowledge under Medicare's limitation of liability provision. These commenters believe that providers and practitioners will be denied their right to due process of law because the provider and practitioner are entitled only to a reconsideration, and are prohibited from obtaining a hearing on medical necessity, reasonableness, and appropriateness of the setting in which services were furnished. Furthermore, the commenters state that since the implementation of a prospective payment system covering inpatient hospital services, limitation of liability and coverage issues are tied so closely together that the provider and practitioner should be able to obtain a hearing on both issues.

Response: This limitation is imposed by section 1155 of the Act, which states that where the reconsideration is adverse a hearing is available only to the beneficiary. However, section 1879 of the Act entitles a provider and practitioner to an administrative hearing of a determination that finds them financially liable for a furnished service, because they knew or should have known that the service would not be covered, but only if the beneficiary is not going to exercise his or her right of appeal.

Also, we believe that due process is quite adequately afforded a provider and practitioner by the rules published today. Under § 466.93, opportunity to discuss proposed initial denial determination, the provider or practitioner is provided with an opportunity to discuss the proposed

initial denial determination with the PRO physician before it is issued, including the nature of the patient's need for health care services and all factors that preclude treatment of the patient as an outpatient or in an alternative level of inpatient care. Then, after the issuance of a denial, the provider or practitioner can again present its side of the argument in a reconsideration, including relevant information not previously made available to the PRO. These procedures for peer review and provider appeals were consistently applied in the PSRO program, which preceded the PRO program.

X. Time Period to Request a Hearing and Date of Request for a Hearing

Comment: One commenter thinks that—(1) The timing of the request for a hearing under proposed § 473.54(b) should run from the date the reconsidered determination notice was received; and (2) The date of the request for an administrative hearing should be the date postmarked on the request.

Response: We agree. We are changing § 473.42(b) to include these provisions. Also, we are revising proposed § 473.28 (now § 473.20) to be consistent with Medicare appeals procedures. The regulations now state that a request for a reconsideration or hearing must be filed within 60 days after the date of receipt of the notice of the initial denial determination or the reconsidered determination, respectively. Receipt is presumed to be five days after the date of the notice. Further, we are deleting proposed § 473.24(a)(7). Section 473.24(a)(7) referred to nonreceipt of notice as a good cause for late filing. The time limit for receipt only begins with the receipt of a notice; therefore, nonreceipt is a separate issue from good cause for late filing.

Regarding the second comment, a request for a reconsideration or a hearing will be considered timely if the postmark date of the request is within the period for timely filing. We have added this to §§ 473.20 and 473.42.

Y. Amount in Dispute Necessary for Obtaining a Hearing

Comment: Two commenters want to know why we require that \$200 be in dispute to permit some hearings while only \$100 need be in dispute to permit other hearings.

Response: Section 1155 of the Act requires that at least \$200 must be in controversy for a beneficiary to obtain a hearing by an ALJ after a PRO reconsidered determination. However, limitation of liability determinations are made under section 1879 of the Act, not

title XI. Section 1869(b) of the Act permits a beneficiary to seek a hearing by an ALJ of a reconsidered limitation of liability determination under Part A where the amount in controversy is \$100 or more, and section 1879(d) of the Act gives a provider or practitioner the same appeal rights a beneficiary has to appeal a limitation of liability determination when the beneficiary does not exercise appeal rights.

Z. Reopening a Reconsidered Determination for Fraud or Similar Abusive Practice

Comment: One commenter is concerned that the proposed § 473.60 (now § 473.48) extends reopenings to include reconsiderations obtained through similar abusive practice that does not support a formal finding of fraud. This commenter is afraid that this gives the PRO wide discretionary authority to reopen a reconsidered determination at any time depending upon the PRO's subjective definition of similar abusive practice.

Response: Many practices that do not involve a fraudulent act nevertheless result in unnecessary and wasteful expenditure of Medicare funds. In order to increase efficiency of the Medicare program, we believe it is appropriate to permit reopenings at any time such practices are discovered.

IV. Changes to the NPRM

Based on the comments received and other considerations, we are making the following changes to the proposed rule. We have also made technical changes to the proposed regulations to correct drafting errors and to simplify and clarify certain sections:

A. Changes Based on Public Comments

- We have added a new § 473.14(c)(1) to state that the granting of grace days is not subject to reconsideration.

- We have changed proposed § 473.18(d) (now § 473.15) to require a PRO to review changes as a result of a DRG validation that caused an assignment of a different DRG, if the review is requested by a provider or practitioner.

- In § 473.15(a)(3), we require the individual who reviews changes in DRG procedural or diagnostic information to be a physician, and we require the individual who reviews changes in DRG coding to be qualified through training and experience with ICD-9-CM coding.

- We have changed proposed § 473.20 (now § 473.18) to prohibit a beneficiary from requesting a reconsideration from a PRO representative at the health care facility because this may place an unreasonable burden on the hospital.

- The proposed § 473.28 (now § 473.20) now explains that a beneficiary has three days in which to request an expedited reconsideration of a preadmission denial or the normal 60 day period to request a regular reconsideration of a preadmission denial.

- Also, under § 473.20, a request for a reconsideration must be filed within 60 days after receipt of the notice of the initial determination, and we presume receipt to occur five days after the date of the notice. In addition, a request for a reconsideration is considered filed on the day it is postmarked.

- Proposed § 473.24 (now § 473.28) has been revised to prohibit the individual who made the initial denial determination from also making the reconsidered determination.

- Under proposed § 473.32 (now § 473.24) the PRO has to provide the parties only with the information that was used to support the initial denial determination.

- Proposed § 473.42 (now § 473.32) has been revised to require a PRO to complete its reconsideration and send written notice within 30 working days after receipt of a request for reconsideration from a provider or practitioner.

- Proposed § 473.44 (now § 473.34) has been revised to require that the PRO provide written notification of its reconsidered determination to the intermediary or carrier, as appropriate, within 30 days of the determination, if the initial denial determination has been modified or reversed.

- Proposed § 473.54 (now § 473.42) restates Medicare policy that a request for a hearing must be filed within 60 days after receipt of the notice of the reconsidered determination and that we presume receipt to occur five days after the date of the notice. In addition a request for a hearing is considered filed on the day it is postmarked.

B. Technical Changes

- We have reorganized the regulations text. Many procedures have been rewritten for clarity and are in regulations sections that are different from the proposed sections.

- We now refer to initial determinations that may be appealed on the issues of reasonableness or medical necessity of the services or appropriateness of the inpatient setting as initial denial determinations. We now refer to a review of a DRG coding change rather than a reconsideration of a DRG coding change so that it will be clear that no additional appeal is available.

• We have removed most references to the limitation of liability determinations under section 1879 of the Act and have specified that the rules under 42 CFR Part 405, Subparts, G or H, for reconsiderations and appeals of limitation of liability determinations in the Medicare program are applicable instead of the procedures in this rule.

• In proposed § 473.60 (now § 473.44) Determining the amount in controversy, we now indicate that the dismissal of a request for an ALJ hearing occurs when the ALJ determines that the amount in controversy is less than \$200. In the proposal, we did not clearly indicate when the dismissal occurs.

V. Impact Analysis

A. Executive Order 12291

We have determined that these final regulations are not likely to result in an annual economic effect of \$100 million or more, or meet other threshold criteria of section 1(b) of the Executive Order. Executive Order 12291 requires that a regulatory impact analysis be performed on any major rule. A "major rule" is defined as one which will:

- Result in annual effect on the national economy of \$100 million or more;
- Result in a major increase in costs or prices for consumers, any industries, any government agencies, or any geographic regions; or
- Have significant adverse effects on competition, employment, investment, productivity, innovation or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or import markets.

This final rule is one of several efforts to promote a more efficient peer review program. Specifically, we streamlined the PRO reconsideration process primarily by not prescribing the details of that process. Our experience has shown that due to our stringent review instructions, the PSRO reconsideration process has taken the form of an evidentiary hearing. This is a relatively costly process as it can involve various professionals and numerous staff hours to complete the reconsideration review. PROs now have the option of conducting the reconsideration through oral presentations and a review of documentation, or through a review of documentation only.

We believe that this final rule will allow for administrative ease through the deletion of the requirement for professional consultation at the administrative hearing level and by having PROs make all limitation of liability determinations associated with their initial denials. These changes will

be less costly to the program, and may result in some negligible savings.

At this time, we can not estimate precisely the increase or decrease in the number of reconsiderations, administrative appeals and judicial reviews that will occur in fiscal year 1985. We do not believe that this final rule will either encourage or discourage appeals. Since we assume that there will not be a significant incremental change in the number of reconsiderations and appeals, we conclude that this final rule is not likely to result in an annual economic effect that will meet any of the threshold criteria of the Order.

B. Regulatory Flexibility Act

The Secretary certifies under 5 U.S.C. 605(b), enacted by the Regulatory Flexibility Act of 1980, Pub. L. 96-354, that these regulations will not have a significant economic impact on a substantial number of small entities. The reason for this certification is that although the regulations will reduce the costs of the peer review reconsideration and appeals process, we do not expect the reduction to be significant.

We do not believe that providers will be significantly affected by these regulations because the total number of peer review reconsidered determinations and appeals currently average less than one reconsideration or appeal per provider per year. As noted above, we do not expect a significant incremental change in the number of reconsiderations and appeals in future fiscal years. Therefore, providers will not incur significant additional costs because of these provisions.

C. Paperwork Reduction Act of 1980

Sections 473.18, 473.34, 473.36 and 473.42 of this final rule impose information collection requirements on the public. They are subject to review by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3504-3507). We are seeking OMB approval of these requirements under section 3507 of that Act. When we obtain OMB approval, we will publish a notice in the Federal Register. The public need not comply with those sections of the regulations until OMB approval is obtained. Comments on these requirements should be sent directly to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., Washington, D.C., Attn: Fay Iudicello.

VI. List of Subjects in 42 CFR Part 473

Administrative practice and procedure, Health care, Health professions, Professional standards

review organizations (PSRO), Reconsiderations, Utilization and quality control, Peer review organizations (PRO).

42 CFR Part 473 is amended as set forth below:

A. The table of contents for Chapter IV, Subchapter D is amended by revising the title of Part 473 to read as follows:

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Part

• • • • •

Subchapter D—Peer Review Organizations

• • • • •

473 Reconsiderations and Appeals.

• • • • •

B. 42 CFR Part 473 is amended as follows:

1. The title of Part 473 is revised to read as follows:

PART 473—RECONSIDERATIONS AND APPEALS

2. The table of contents is amended to reflect the establishment of a new Subpart A to encompass §§ 473.1—473.6 and the addition of a new Subpart B; and to revise the authority citation to read as follows:

Subpart A—PSRO Reconsiderations and Appeals

Sec.

- 473.1 Applicability.
- 473.2 Right to reconsideration review and hearing.
- 473.3 Utilization of procedures under Title XVIII, Part A, hearing procedures.
- 473.4 Professional consultation.
- 473.5 Determining amount in controversy in case of proposed services.
- 473.6 Right of judicial review.

Subpart B—Utilization and Quality Control Peer Review Organization (PRO) Reconsiderations and Appeals

- 473.10 Scope.
- 473.12 Statutory basis.
- 473.14 Applicability.
- 473.15 PRO review of changes resulting from DRG validation.
- 473.16 Right to reconsideration.
- 473.18 Location for submitting requests for reconsideration.
- 473.20 Time limits for requesting reconsideration.
- 473.22 Good cause for late filing of a request for a reconsideration or hearing.
- 473.24 Opportunity for a party to obtain and submit information.
- 473.26 Delegation of the reconsideration function.
- 473.28 Qualifications of a reconsideration reviewer.

- 473.30 Evidence to be considered by the reconsideration reviewer.
- 473.32 Time limits for issuance of the reconsidered determination.
- 473.34 Notice of a reconsidered determination.
- 473.36 Record of reconsideration.
- 473.38 Finality of a reconsidered determination.
- 473.40 Beneficiary's right to a hearing.
- 473.42 Submitting a request for a hearing.
- 473.44 Determining the amount in controversy for a hearing.
- 473.46 Appeals Council and judicial review.
- 473.48 Reopening and revision of a reconsidered determination or a hearing decision.

Authority: Sec. 1102 of the Social Security Act, 42 U.S.C. 1302. Subpart A is also issued under sec. 150 of Pub. L. 97-248, 42 U.S.C. 1320c note. Subpart B is also issued under sections 1154(a), 1155, 1866(a), 1871, and 1879 of the Social Security Act, 42 U.S.C. 1320c-3(a), 1320c-4, 1395cc(a), 1395hh, and 1395pp.

3. A new Subpart B is added to read as follows:

Subpart B—Utilization and Quality Control Peer Review Organization (PRO) Reconsiderations and Appeals

§ 473.10 Scope.

This subpart establishes the requirements and procedures for—

(a) Reconsiderations conducted by a Utilization and Quality Control Peer Review Organization (PRO) or its subcontractor or initial determinations concerning services furnished or proposed to be furnished under Medicare;

(b) Hearings and judicial review of reconsidered determinations; and

(c) PRO review of a change in diagnostic and procedural coding information.

§ 473.12 Statutory basis.

(a) Under section 1155 of the Act—

(1) A Medicare beneficiary, a provider, or an attending practitioner who is dissatisfied with a PRO initial denial determination made under the provisions of section 1154 of the Act, that services furnished or proposed to be furnished are not reasonable, necessary, or delivered in the most appropriate setting, is entitled to a reconsideration by the PRO that made the initial denial determination;

(2) A Medicare beneficiary is entitled to a hearing by an administrative law judge (ALJ) if \$200 or more is still in controversy after a reconsidered determination; and

(3) A Medicare beneficiary is entitled to judicial review of a final determination of the Department if \$2,000 or more is still in controversy.

(b) Under section 1866(a)(1)(F) of the Act, a hospital that is reimbursed by the

Medicare program must maintain an agreement with a PRO under which the PRO will review the validity of diagnostic information furnished by the hospital.

§ 473.14 Applicability.

(a) *Basic provision.* This subpart applies to reconsiderations and hearings of a PRO initial denial determination involving the following issues:

- (1) Reasonableness of services.
- (2) Medical necessity services.
- (3) Appropriateness of the inpatient setting in which services were furnished or are proposed to be furnished.

(b) *Concurrent appeal.* A reconsideration or hearing provided under this subpart fulfills the requirements of any other review, hearing, or appeal under the Act to which a party may be entitled with respect to the same issues.

(c) *Nonapplicability of rules to related determinations.* (1) A PRO may not reconsider its decision whether to grant grace days.

(2) Limitation of liability determinations on excluded coverage of certain services are made under section 1879 of the Act. Initial determinations under section 1879 and further appeals are governed by the reconsideration and appeal procedures in Part 405, Subpart G of this chapter for determinations under Medicare Part A, and Part 405, Subpart H of this chapter for determinations under Medicare Part B. References in those subparts to initial and reconsidered determinations made by an intermediary, carrier or HCFA mean initial and reconsidered determinations made by a PRO.

§ 473.15 PRO review of changes resulting from DRG validation.

(a) *General rules.* (1) A provider or practitioner dissatisfied with a change to the diagnostic or procedural coding information made by a PRO as a result of DRG validation under section 1866(a)(1)(F) of the Act is entitled to a review of that change if—

- (i) The change caused an assignment of a different DRG; and
- (ii) Resulted in a lower payment.

(2) A beneficiary may obtain a review of a PRO DRG coding change only if that change results in noncoverage of a furnished service.

(3) The individual who reviews changes in DRG procedural or diagnostic information must be a physician, and the individual who reviews changes in DRG coding must be qualified through training and experience with ICD-9-CM coding.

(b) *Procedures.* Procedures described in §§ 476.18-473-36, 473.38(b), and

473.48 (a) and (c) for a PRO reconsideration or reopening also apply to PRO review of a DRG coding change.

(c) *Finality of review.* No additional review or appeal for matters governed by paragraph (a) of this section is available.

§ 473.16 Right to reconsideration.

A beneficiary, provider or practitioner who is dissatisfied with a PRO initial denial determination on one of the issues specified in § 473.14(a) has a right to a reconsideration of that determination by the PRO that made the initial denial determination.

§ 473.18 Location for submitting requests for reconsideration.

(a) *Beneficiaries.* Except as provided in paragraph (c) of this section concerning requests for expedited reconsideration, a beneficiary who wishes to obtain a reconsideration must submit a written request to one of the following:

- (1) The PRO or the PRO subcontractor that made the initial determination.
- (2) An SSA District Office.
- (3) A Railroad Retirement Board Office, if the beneficiary is a railroad retiree.

(b) *Others.* A provider, physician or other practitioner that wishes to obtain reconsideration must submit a written request to the PRO or PRO subcontractor that made the initial determination.

(c) *Expedited reconsideration.* A request for an expedited reconsideration of a preadmission denial determination must be submitted directly to the PRO.

§ 473.20 Time limits for requesting reconsideration.

(a) *Basic rules.* (1) Except for a request for expedited reconsideration as provided in paragraph (c) of this section, or a late request with good cause under § 473.22, a dissatisfied party must file a request for reconsideration within 60 days after receipt of the notice of an initial determination.

(2) The date of receipt of the notice of the initial determination is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(3) A request is considered filed on the date it is postmarked.

(b) *Late filing of request.* A PRO will accept a request filed after 60 days after receipt of the notice of the initial determination if the PRO finds under the criteria set forth in § 473.22 that there was good cause for the party's failure to file a timely request.

(c) *Request for expedited reconsideration.* A request for an expedited reconsideration under

§ 473.18(c) must be submitted within three days after receipt of the notice of the initial denial determination.

§ 473.22 Good cause for late filing of a request for a reconsideration or hearing.

(a) *General Rule.* In determining whether a party has good cause for not filing a request for reconsideration or hearing timely, the PRO or ALJ, respectively, must consider the following:

(1) What circumstances kept the party from making the request on time.

(2) Whether an action by the PRO misled the party.

(3) Whether the party understood the requirements of the Act as affected by amendments to the Act, other legislation, or court decisions.

(b) *Examples.* Examples of circumstances in which good cause may exist include, but are not limited to, the following:

(1) A party was seriously ill and was prevented from requesting a reconsideration in person, through another person, or in writing.

(2) There was a death or serious illness in a party's immediate family.

(3) Important records were accidentally destroyed or damaged by fire or other cause.

(4) A party made a diligent effort but could not find or obtain necessary relevant information within the appropriate time period.

(5) A party requested additional information to further explain the determination within the time limit, and requested reconsideration within 60 days of receiving the explanation (or within 30 days for an Appeals Council hearing).

(6) The PRO gave the party incorrect or incomplete information about when and how to request a reconsideration or hearing.

(7) A party sent the request to another Government agency in good faith within the time limit, but the request did not reach an office authorized to receive the request until after the time period had expired.

(8) Other unusual or unavoidable circumstances exist that—

(i) Show that a party could not have known of the need to file timely; or

(ii) Prevented a party from filing timely.

§ 473.24 Opportunity for a party to obtain and submit information.

(a) Subject to the rules concerning disclosure of PRO information in section 1160 of the Act, at the request of a provider, practitioner or beneficiary, the PRO must provide an opportunity for examination of the material upon which the initial denial determination was based. The PRO may not furnish a

provider, practitioner or beneficiary with—

(1) A record of the PRO deliberation; or

(2) The identity of the PRO review coordinators, physician advisors, or consultants who assisted in the initial denial determination without their consent.

(b) The PRO may require the requester to pay a reasonable fee for the reproduction of the material requested.

(c) The PRO must provide a party with an opportunity to submit new evidence before the reconsidered determination is made.

§ 473.26 Delegation of the reconsideration function.

A PRO may delegate the authority to reconsider an initial determination to a nonfacility subcontractor, including the organization that made the initial determination as a PRO subcontractor.

§ 473.28 Qualifications of a reconsideration reviewer.

A reconsideration reviewer must be someone who is—

(a) Qualified under § 466.98 of this chapter to make an initial determination.

(b) Not the individual who made the initial denial determination.

(c) A specialist in the type of services under review, except where meeting this requirement would compromise the effectiveness or efficiency of PRO review.

§ 473.30 Evidence to be considered by the reconsideration reviewer.

A reconsidered determination must be based on—

(a) The information that led to the initial determination;

(b) New information found in the medical records; or

(c) Additional evidence submitted by a party.

§ 473.32 Time limits for issuance of the reconsidered determination.

(a) *Beneficiaries.* If a beneficiary files a timely request for reconsideration of an initial denial determination, the PRO must complete its reconsidered determination and send written notice to the beneficiary within the following time limits—

(1) Within three working days after the PRO receives the request for reconsideration if—

(i) The beneficiary is still an inpatient in a hospital for the stay in question when the PRO receives the request for reconsideration; or

(ii) The initial determination relates to institutional services for which admission to the institution is sought, the initial determination was made

before the patient was admitted to the institution; and a request was submitted timely for an expedited reconsideration.

(2) Within 10 working days after the PRO receives the request for reconsideration if the beneficiary is still an inpatient in a SNF for the stay in question when the PRO receives the request for reconsideration.

(3) Within 30 working days after the PRO receives the request for reconsideration if—

(i) The initial determination concerns ambulatory or noninstitutional services;

(ii) The beneficiary is no longer an inpatient in a hospital or SNF for the stay in question; or

(iii) The beneficiary does not submit a request for expedited reconsideration timely.

(b) *Providers or practitioners.* If the provider or practitioners files a request for reconsideration of an initial determination, the PRO must complete its reconsidered determination and send written notice to the provider or practitioner within 30 working days.

§ 473.34 Notice of a reconsidered determination.

(a) *Notice to parties.* A written notice of a PRO reconsidered determination must contain the following:

(1) The basis for the reconsidered determination.

(2) A detailed rationale for the reconsidered determination.

(3) A statement explaining the Medicare payment consequences of the reconsidered determination.

(4) A statement informing the parties of their appeal rights, including the information concerning what must be included in the request for hearing, the amount in controversy, locations for submitting a request for an administrative hearing and the time period for filing a request.

(b) *Notice to payers.* (1) A PRO must provide written notice of its reconsidered determination to the appropriate Medicare intermediary or carrier within 30 days if the initial determination is modified or reversed.

(2) This notice must contain adequate information to allow the intermediary or carrier to locate the claim file. This must include the name of the beneficiary, the Health Insurance Claim Number, the name of the provider, date of admission, and dates or services for which Medicare payment will not be made.

§ 473.36 Record of reconsideration.

(a) *PRO requirements.* A PRO must maintain the record of its reconsideration until the later of the following:

(1) Four years after the date on the

notice of the PRO's reconsidered determination.

(2) Completion of litigation and the passage of the time period for filing all appeals.

(b) *Contents of the record.* The record of the reconsideration must include:

(1) The initial determination.

(2) The basis for the initial determination.

(3) Documentation of the date of the receipt of the request for reconsideration.

(4) The detailed basis for the reconsidered determination.

(5) Evidence submitted by the parties.

(6) A copy of the notice of the reconsidered determination that was provided to the parties.

(7) Documentation of the delivery or mailing and, if appropriate, the receipt of the notice of the reconsidered determination by the parties.

(c) *Confidentiality.* The record of a PRO reconsideration is subject to prohibitions against disclosure of information as specified in section 1160 of the Act.

§ 473.38 Finality of a reconsidered determination.

A PRO reconsidered determination is final and binding upon all parties to the reconsideration unless—

(a) A hearing is requested in accordance with § 473.40 and a final rendered; or

(b) The reconsidered determination is later reopened and revised in accordance with § 473.48

§ 473.40 Beneficiary's right to a hearing.

(a) *Amount in controversy.* If the amount in controversy is at least \$200, a beneficiary (but not a provider or practitioner) who is dissatisfied with a PRO reconsidered determination may obtain a hearing by an administrative law judge (ALJ) of the Office of Hearings and Appeals of the SSA.

(b) *Subject matter.* A beneficiary has a right to a hearing on the following issues:

(1) Reasonableness of the services.

(2) Medical necessity of the services;

(3) Appropriateness of the setting in which the services were furnished.

(c) *Governing provisions.* The provisions of Subpart G, Reconsiderations and Appeals under the Hospital Insurance Program, of Part 405 of this chapter apply to hearings and appeals under this subpart unless they are inconsistent with specific provisions in this subpart. References in that Subpart G to initial and reconsidered determinations made by an intermediary, carrier, or HCFA should be read to mean initial and reconsidered determinations made by a PRO.

§ 473.42 Submitting a request for a hearing.

(a) *Where to submit the written request.* A beneficiary who wants to obtain a hearing under § 473.40 must submit a written request to one of the following:

(1) The office of the PRO or PRO subcontractor that made the initial determination.

(2) A SSA District Office.

(3) An office of the Office of Hearings and Appeals of SSA.

(4) An office of the Railroad Retirement Board, in the case of a beneficiary who is a railroad retiree.

(b) *Time limit for submitting a request for a hearing.* (1) The request for a hearing must be filed within 60 days of receipt of the notice of the PRO reconsidered determination, unless the time is extended for good cause as provided in § 473.22.

(2) The date of receipt of the notice of the reconsidered determination is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(3) A request is considered filed on the date it is postmarked.

§ 473.44 Determining the amount in controversy for a hearing.

(a) After a party has submitted a request for a hearing, the ALJ determines the amount in controversy in accordance with § 405.740 of this chapter.

(b) If the ALJ determines that the amount in controversy is less than \$200, the ALJ, without holding a hearing, notifies the parties to the hearing that the parties have 15 calendar days to submit additional evidence to prove that the amount in controversy is at least \$200.

(c) At the end of the 15-day period, if the ALJ determines that the amount in controversy is less than \$200, the ALJ, without holding a hearing, dismisses the request for a hearing without ruling on the substantive issues involved in the appeal and notifies the parties to the hearing and the PRO that the PRO reconsidered determination is conclusive for Medicare payment purposes.

§ 473.46 Appeals Council and judicial review.

(a) The circumstances under which the Appeals Council of the Social Security Administration will review an ALJ hearing decision or dismissal are specified in 20 CFR 404.970. Cases the Appeals Council will review.

(b) If \$2,000 or more is in controversy, a party may obtain judicial review of an Appeals Council decision, or an ALJ hearing decision if a request for review by the Appeals Council was denied, by filing a civil action under the Federal

Rules of Civil Procedure within 60 days after the date the party received notice of the Appeals Council decision or denial.

§ 473.48 Reopening and revision of a reconsidered determination or a hearing decision.

(a) *PRO reopenings—(1) General rule.* A PRO or PRO subcontractor that made a reconsidered determination, or conducted a review of a DRG change as described in § 473.15, that is otherwise final, may reopen and revise the reconsidered determination or review, either on its own motion or at the request of a party, within one year from the date of the reconsidered determination or review.

(2) *Extension of time limit.* A PRO or PRO subcontractor may reopen and revise its reconsidered determination, or its review of a DRG change as described in § 473.15, that is otherwise final, after one year but within four years of the date of the determination or review if—

(i) The PRO receives new material evidence;

(ii) The PRO erred in interpretation or application of Medicare coverage policy;

(iii) There is an error apparent on the face of the evidence upon which the reconsidered determination was based; or

(iv) There is a clerical error in the statement of the reconsidered determination.

(b) *ALJ and Appeals Council Reopening—Applicable procedures.* The ALJ or the Appeals Council, whichever made the final decision, may reopen and revise the decision in accordance with the procedures set forth in § 405.750(b) of this chapter, which concerns reopenings and revisions under Subpart G of Part 405 of this chapter.

(c) *Fraud or similar abusive practice.* A reconsidered determination, a review of a DRG change, or a decision of an ALJ or the Appeals Council may be reopened and revised at any time, if the reconsidered determination, review, or decision was obtained through fraud or a similar abusive practice that does not support a formal finding of fraud.

(Catalog of Federal Domestic Assistance Program No. 13.773, Medicare—Hospital Insurance; No. 13.774, Medicare—Supplementary Medical Insurance)

Dated: December 6, 1984.

Carolyn K. Davis,
Administrator, Health Care Financing Administration.

Approved: January 28, 1985.

Margaret M. Heckler,
Secretary.

[FR Doc. 85-9003 Filed 4-11-85; 2:43 pm]
BILLING CODE 4120-01-M

**Wednesday
April 17, 1985**

Part IV

**Department of
Transportation**

Federal Aviation Administration

**14 CFR Parts 61, 63, 65 and 91
Use of Alcohol or Drugs; Final Rule and
Submission to Alcohol Tests,
Supplemental Notice of Proposed
Rulemaking**

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 61, 63, 65, and 91

[Docket No. 21956; Amdt. Nos. 61-74, 63-23, 65-29, and 91-188]

Use of Alcohol or Drugs

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: These amendments establish rules governing the use of alcohol or drugs by any crewmember assigned to perform duty during the operation of an aircraft. In addition to maintaining current provisions regarding the use of alcohol or drugs before serving as a crewmember, it delineates the maximum allowable blood alcohol content level. Crewmembers also will be required to furnish the Administrator with the results of any test that is performed that may indicate the percentage of alcohol in the blood or the presence of drugs in the body when such tests have been taken within 4 hours after acting or attempting to act as a crewmember. Failure to furnish or authorize the release of the results of these tests will result in certificate action or other sanctions. These rules are based, in part, on a National Transportation Safety Board determination that alcohol is a cause or factor in about 40 aircraft accidents annually, almost all of which are fatal. These amendments are intended to facilitate enforcement of the present drug and alcohol regulations and to reduce aircraft accidents and incidents attributable to consumption of alcoholic beverages and the use of drugs. For this same purpose, the FAA is proposing elsewhere in this issue of the Federal Register to require crewmembers to submit to tests for alcohol given by law enforcement officers under certain circumstances.

EFFECTIVE DATE: June 17, 1985.

FOR FURTHER INFORMATION CONTACT: Mike Sacrey or Roger Baker, Federal Aviation Administration, General Aviation & Commercial Division, Operations Branch (AFO-820), 800 Independence Avenue, SW., Washington, D.C. 20591; Phone: (202) 426-8194.

SUPPLEMENTARY INFORMATION:**Background**

Rules relating to the use of drugs and the consumption of alcoholic beverages in connection with aircraft operations are set forth in § 91.11 of the Federal Aviation Regulations (FAR) (14 CFR 91.11). This section provides that no

person may act as a crewmember of a civil aircraft (1) within 8 hours after the consumption of any alcoholic beverage, (2) while under the influence of alcohol, or (3) while using any drug that affects the faculties in any way contrary to safety. "Crewmember" is defined in FAR Part 1 as "a person assigned to perform duty in an aircraft during flight time." A pilot, flight engineer, flight navigator, or flight attendant is such a person.

The National Transportation Safety Board (NTSB) has recommended that the FAA add an implied consent clause to the FAR and specify an alcohol level at which a pilot would be considered to be under the influence. The General Accounting Office (GAO) made similar recommendations in a Report to Congress by the Comptroller General entitled "Stronger Federal Aviation Administration Requirements Needed to Identify and Reduce Alcohol Use Among Civilian Pilots" (CED-78-58; March 20, 1978).

The FAA is concerned about the serious hazard, during aircraft operations, resulting from impairment of the pilot's faculties due to alcohol. Even small amounts of alcohol affect judgment, coordination, performance, and reaction time. Vision, hearing, touch, information processing, memory, reasoning, and attention span also may be affected by alcohol consumption. Inflight testing of experienced professional aviators has shown that even 40 milligrams percent by weight of alcohol in the blood exerts detrimental effects on performance which are incompatible with flight safety (Report on "The Effects of Alcohol on Pilot Performance During Instrument Flight" by Aviation Medicine Research Laboratory, Ohio State University; FAA Report No., FAA-AM-72-4). Moreover, the effects of alcohol on performance are additive to the expected hypoxic effects with increased altitude.

The ability of a crewmember to function without impairment of performance is an essential element in the safety of flight and in the effectiveness of the air traffic system. Since alcohol can affect the ability of a crewmember to function properly and thus is detrimental to aviation safety, the FAA must make every reasonable effort to prevent those who are under the influence of alcohol from flying.

For a number of years the FAA has expended a substantial amount of time and funds trying to educate the flying public to this danger. As part of this effort, the agency worked closely with groups such as the Aircraft Owners and Pilots Association and the Air Line Pilots Association to establish effective

educational programs. Although these programs have been beneficial, the problem still remains. There continues to be a significant number of accidents each year where alcohol is found to be a factor or cause. For example, in 1979, according to an NTSB study, U.S. general aviation aircraft were involved in 34 accidents where alcohol impairment was a cause/factor, 30 of which were fatal. This represents an 88 percent fatality rate for alcohol-related accidents as compared to a 17 percent fatality rate for all of general aviation. In addition, in recent Congressional testimony, the FAA stated that there were 155 reported accidents from 1980 through 1982 in which evidence of drug carriage was found. Therefore, the FAA must take additional steps to reduce the frequency of these accidents by strengthening the rules relating to the use of alcohol and drugs.

The FAA published Notice of Proposed Rulemaking (NPRM) No. 81-9 on July 27, 1981 (46 FR 38480), proposing regulations that were intended to deter persons from acting or attempting to act as a crewmember while under the influence of alcohol or drugs and to provide a basis for necessary enforcement action. Seventy-four comments were received as a result of the NPRM. These amendments reflect both FAA consideration of those comments and its continuing responsibility to uphold and encourage safety in air commerce.

Blood Alcohol Content

Currently, § 91.11(a) (1) and (2) provides that no person may act as a crewmember of a civil aircraft within 8 hours after the consumption of any alcoholic beverage or while under the influence of alcohol. In response to the recommendations from the NTSB and the GAO, Notice 81-9 proposed a further amendment to that section to prohibit acting as a crewmember while having 40 milligrams percent or more by weight of alcohol in the blood.

Some commenters oppose the proposed 40 milligrams, recommending that a level of 100 milligrams percent by weight, as used in many state motor vehicle statutes, be used instead. A number of other commenters agree that the proposed level is appropriate in view of the high performance required of pilots and the additive effects of alcohol at higher altitudes.

The FAR currently requires strict separation between alcohol and flying. The consumption of any alcohol within 8 hours before acting as a crewmember is prohibited. The FAA is adding a new prohibited level of alcohol which can be

used to take enforcement action against a crewmember even where witness statements alone are insufficient to establish violations of the 8-hour rule or the under-the-influence rule. The FAA proposed a value of 40 milligrams percent by weight based on the latest and most extensive study and research, at the time of the proposal, into the amount of impairment induced by specific levels of alcohol content within the blood. Inflight testing of experienced professional aviators showed that 40 milligrams percent by weight of alcohol in the blood produced detrimental effects on performance that were incompatible with flight safety. Based on the available evidence, the FAA proposed that 40 milligrams percent by weight of alcohol in the blood be incorporated into the regulations. It is important to note, however, that it is possible to be under the influence of alcohol, or to have 40 milligrams or more percent by weight of alcohol in the blood, or both, more than 8 hours after consuming an alcoholic beverage.

Some commenters question what the term "40 milligrams percent by weight of alcohol" means, suggesting that a more common term be used. That term means 40 milligrams of alcohol in a sample of 100 milliliters of blood. This is equivalent to .04 percent alcohol in the blood. States, in their motor vehicle statutes, normally use percent to describe blood alcohol levels. The FAA agrees that it is appropriate to use a term which is more commonly understood. The rule, as adopted, thus expresses the prohibited blood alcohol level as ".04 percent."

Several commenters note that it is possible to have a blood alcohol level higher than .04 percent more than 8 hours after consuming an alcoholic beverage. This is true and is one reason why the "under the influence" provision and the ".04 percent" provision are needed in § 91.11 in addition to the 8-hour rule.

Breath Test

Notice 81-9 proposed criteria for requiring a crewmember to submit to a chemical test of the breath for blood alcohol levels. Such a test would have corroborated other evidence, such as a person's appearance or conduct, and it was anticipated that it would have aided in enforcing the regulations. The test would have been conducted by a representative of the Administrator on reasonable grounds to believe that the crewmember had violated § 91.11.

After further consideration, it appears that it would be impractical to have representatives of the Administrator equipped and trained to conduct the

tests. As a number of commenters state, due to staffing levels and the large geographic areas covered by district offices, FAA inspectors are rarely able to respond to a report of a crewmember who is suspected of violating § 91.11 quickly enough to make a breath test useful. Breath testers would not be used often enough by FAA inspectors to warrant the expense of the testers and initial and recurrent training of the inspectors. There appears to be no practical method of requiring suspected violators to submit to a chemical test of the breath conducted by a representative of the Administrator. For this reason, the proposals requiring submission to a chemical test of the breath when requested by the Administrator and the consequences of refusal to submit to such a test are withdrawn.

Many commenters note that state and local law enforcement officers are often the first officials on the scene of an incident. Many state or local law enforcement officers are authorized, trained, and equipped to conduct, or are authorized to direct others to conduct, a chemical test of the breath or other test to determine the presence of alcohol or drugs in the body. The Administrator is proposing, in a supplemental notice of proposed rulemaking (published elsewhere in this Federal Register), that crewmembers be required to submit to such a test under certain conditions when requested by a law enforcement officer. This amendment allows the Administrator to request the results of these tests, as well as medical tests, based on reasonable grounds for believing that the person acted, or attempted to act, as a crewmember of a civil aircraft in violation of § 91.11. The Administrator's ability to elicit the results of these tests should act as a positive deterrent to those persons who might otherwise attempt to act as a crewmember while under the influence of alcohol or drugs.

Attempting To Act as a Crewmember

Notice 81-9 also proposed to prohibit attempting to act as a crewmember under any of the criteria specified in § 91.11(a). Several commenters oppose this proposal, arguing that it may be difficult to establish when a person is attempting to act as a crewmember. However, circumstances do exist under which a person may be found to have attempted to act as a crewmember, such as when a person enters an aircraft to assume his or her duties as a crewmember while demonstrating by manner or physical indications that he or she appears to be intoxicated or under the influence of drugs. In such a

case, an FAA inspector will not have the dilemma of choosing between trying to dissuade a person from acting as a crewmember or waiting for that person to actually execute his or her duties as a crewmember before a violation can be established.

One commenter questions whether flight attendants should be subject to the provisions of § 91.11, stating that there appears to be no history of accidents caused by flight attendants acting in violation of this section. As crewmembers, flight attendants should not be under the influence of drugs or alcohol while on duty since it would affect passenger safety. For this reason, flight attendants have been included in § 91.11 since it was first proposed. Their inclusion in this final rule is consistent with the purpose of the regulation.

Alcohol and Drug Test Results

Notice 81-9 proposed to amend § 91.11 to require that on the Administrator's request, a crewmember must furnish to the Administrator the results of any medical tests taken that indicate the level of alcohol in the blood or the presence of drugs in the body. The request would be made in the course of an enforcement investigation and would be based on reasonable grounds for believing that the person may have acted or attempted to act as a crewmember of a civil aircraft in violation of § 91.11(a). For a person to be required to submit the results of such a medical test, the test must have been given within 4 hours after the person acted or attempted to act as a crewmember. Substantial penalties were also proposed in §§ 61.16 and 63.12(a) for refusal to furnish the requested medical test results.

One commenter states that the 4-hour time period in which the medical test would have to be given is too long and suggests that a person should only be required to produce the results of tests conducted within 1 hour after acting or attempting to act as a crewmember. However, scientifically valid results can be obtained in the 4-hour time period proposed. Further, the 1-hour limit suggested would substantially reduce the usefulness of the rule since it is anticipated that it often will be more than 1 hour between the act and the time the test is taken. This amendment should allow the Administrator to obtain more easily the results of hospital or medical tests performed on a crewmember following an accident or incident.

As discussed under the section entitled "Breath Test," these amendments also allow the

Administrator to request the results of tests conducted in accordance with Federal, state, or local laws if there is reason to believe the person may have violated § 91.11. Therefore, § 91.11, as adopted, requires that a crewmember furnish or authorize the release of the results of tests taken under the circumstances described. It should be emphasized, however, that the rules as adopted here do not permit the Administrator to require a person to submit to tests to determine the presence of alcohol or drugs. Note that this amendment does not in any way affect the Administrator's authority to request information under § 67.31 regarding a person's qualification for a medical certificate.

Eligibility After Drug Conviction

Sections 61.15, 63.12, and 65.12 currently provide that no person who is convicted of violating any Federal or state statute relating to the growing, processing, sale, disposition, possession, transportation, or importation of narcotic drugs, marihuana, or depressant or stimulant drugs or substances is eligible for any certificate or rating issued under Part 61, 63, or 65 for a period of 1 year after final conviction, and that such a conviction is grounds for suspension or revocation of any airman certificate (certificate action) issued under these parts. Notice 81-9 proposed amendments to these sections to provide that a conviction for the violation of a Federal or state statute relating to drugs would be grounds for disqualification or certificate action only when the violation involved the use of an aircraft. The proposal was an attempt to remove disqualification for those convictions that do not evidence a disposition towards the irresponsible exercise of airman privileges.

A number of commenters oppose these proposed amendments, stating that while an airman's violation of a drug statute may not have involved the use of an aircraft, it may still indicate a lack of the high standards of integrity, responsibility, and compliance attitude required of airmen. The FAA has reconsidered the proposal in the light of these comments. As indicated by several commenters, violations of the drug laws as set forth in the rule may indicate that the applicant would not be compliance-minded regarding the many safety rules in aviation. The courts have supported this view. The United States Court of Appeals for the Ninth Circuit affirmed the revocation of the private pilot certificate held by a man who had been convicted of possessing marihuana for sale. The court held that there was a rational relationship between a

conviction for possessing drugs for sale and the potential for unsafe use of an aircraft for drug smuggling in the future. *Walters v. McLucas*, 597 F.2d 1230 (9th Cir. 1979). In another case, the United States Court of Appeals for the District of Columbia Circuit affirmed the revocation of the private pilot certificate of a person who had been convicted of conspiring to import marihuana, even though an aircraft had not been used in illegal or unsafe operations. This court held that there is a rational connection between past drug trafficking and future unsafe aircraft operations. *Rahm v. NTSB*, No. 74-1959 (D.C. Cir. Oct. 1, 1975) (memorandum opinion). The FAA agrees; therefore, this proposal is withdrawn to allow the Administrator to maintain his regulatory authority to take certificate action, when appropriate, against airmen who have been convicted of violating drug laws, whether or not that violation involved the use of an aircraft. This rule is consistent with the President's efforts to combat the illegal use and transportation of drugs.

Sections 61.15(a), 63.12(a), and 65.12(a) also currently make a person ineligible for a new certificate or rating for 1 year after final conviction. These sections make it mandatory that the Administrator deny an application for a new certificate or rating for 1 year after the date of the conviction. However, the current rule provides for but does not require the suspension or revocation of an existing certificate; rather, the Administrator may refrain from such action as appropriate. To provide this same flexibility to applicants for a new certificate or rating, the notice proposed to provide that such a conviction is "grounds for" denial rather than to provide that a conviction makes the airman ineligible for a certificate. The intent of the proposal is adopted. By stating such a conviction "is grounds for" denial, the Administrator may use discretion in determining eligibility for a certificate or rating.

There appears to be some confusion over the wording of §§ 61.15(a), 63.12(a), and 65.12(a) regarding the phrase "period of up to 1 year after the date of final conviction." It was not clear to some commenters whether the 1-year period referred to the time in which an application could be denied by the Administrator (that is, in the nature of a statute of limitations) or to the maximum duration of the sanction. The proposal was meant to provide that the denial could last for up to 1 year after the final conviction but not beyond that date. The rule, as adopted, is reorganized to clarify this intent.

As proposed in Notice 81-9, §§ 63.12(b) and 65.12(b) did not provide that the commission of an act prohibited by § 91.11(a) or § 91.12(a) is grounds for revocation or suspension of a certificate or rating issued under Part 63 or Part 65, respectively. These provisions are contained in the current rule and were not intended to be removed. Therefore, §§ 63.12(b) and 65.12(b), as adopted, incorporate these provisions.

Notice 81-9 proposed, in §§ 61.16(b) and 63.12(b), a "minimum 1-year" suspension or revocation of a certificate issued under Part 61 or Part 63, respectively, for violation of § 91.11 (c) or (d). The "minimum 1-year" is removed because it is inconsistent with the need for flexibility in enforcing the rule, as previously discussed.

Note that on October 19, 1984, the Aviation Drug-Trafficking Control Act was passed (Pub. L. 98-499). This act, in general, requires the Administrator to revoke the certificates of airmen who have committed certain Federal or state drug felonies involving aircraft. In those cases in which the new Act applies, its provisions will be used. In other cases, the current rules, as amended in this final rule, will apply.

Refusal To Carry Intoxicated Persons

Section 91.11(b) presently provides that, except in an emergency, no pilot of a civil aircraft may allow a person who is obviously under the influence of intoxicating liquors or drugs (except a medical patient under proper care) to be carried in that aircraft. Recognizing the difficulty of interpreting the word "obviously," Notice 81-9 proposed to clarify the rule by referring to a person who demonstrates by manner or physical indications that he or she is under the influence of intoxicating liquors or drugs.

Three commenters oppose the proposed changes in the wording of this regulation as it relates to alcohol. One commenter states that the proposed rule is too strict, since it indicates that a passenger who had only one or two drinks would not be permitted on board because that person would be "under the influence." This commenter suggests that the rule only prohibit boarding of passengers whom the pilot has reason to believe will be a danger, such as those who are violent or angry. Another commenter suggests that wording in § 121.575(c) of the FAR has been effective in its application to Part 121 air carriers and should be used in § 91.11(b). Section 121.575(c) states: "No certificate holder may allow any person to board any of its aircraft if that person appears to be intoxicated." The FAA

agrees that the wording "appears to be intoxicated" is appropriate and is more likely to be correctly interpreted. The FAA has therefore added this phrase to the proposed rule and amended § 91.11(b) to provide that no pilot of a civil aircraft may allow any person who appears to be intoxicated, or who demonstrates by manner or physical indication that he or she is under the influence of drugs, to be carried aboard that aircraft.

Regulatory Evaluation

It is expected that these amendments will deter a person from acting or attempting to act as a crewmember while under the influence of alcohol or drugs and will prevent some accidents that might otherwise occur. The exact number, however, is impossible to calculate.

While there might be some minor costs incurred in obtaining the results of tests and submitting them to the Administrator, the economic benefits provided by increased deterrence are greater than the relatively small costs involved.

Conclusion

While a minor cost may be incurred by suspected violators if asked to furnish the results of tests, compliance with these amendments will not impose any other cost or economic burden on airmen. Accordingly, it has been determined that this is not a major regulation under Executive Order 12291. However, this rule is significant under the Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). Since these amendments have a minor cost impact and apply to individuals rather than small entities, I certify that under the criteria of the Regulatory Flexibility Act, these amendments will not have a significant economic impact on a substantial number of small entities. A regulatory evaluation has been prepared for this action and is contained in the regulatory docket. A copy of it may be obtained by contacting the person identified under the caption "FOR FURTHER INFORMATION CONTACT."

List of Subjects

14 CFR Part 61

Airmen, Aircraft pilots, Pilots, Alcohol and alcoholic beverages, Narcotics, Air safety, Safety, Aviation safety, Drug abuse.

14 CFR Part 63

Airmen, Narcotics, Air safety, Safety, Aviation safety, Drug abuse.

14 CFR Part 65

Airmen, Narcotics, Air safety, Safety, Aviation safety, Drug abuse.

14 CFR Part 91

Aviation safety, Safety, Aircraft pilots, Liquor, Narcotics, Pilots.

Adoption of the Amendment

Accordingly, Parts 61, 63, 65, and 91 of the Federal Aviation Regulations (14 CFR Parts 61, 63, 65, and 91) are amended as follows, effective June 17, 1985.

PART 61—CERTIFICATION: PILOTS AND FLIGHT INSTRUCTORS

1. By revising § 61.15 to read as follows:

§ 61.15 Offenses involving alcohol or drugs.

(a) A conviction for the violation of any Federal or state statute relating to the growing, processing, manufacture, sale, disposition, possession, transportation, or importation of narcotic drugs, marihuana, or depressant or stimulant drugs or substances is grounds for—

(1) Denial of an application for any certificate or rating issued under this Part for a period of up to 1 year after the date of final conviction; or

(2) Suspension or revocation of any certificate or rating issued under this part.

(b) The commission of an act prohibited by § 91.11(a) or § 91.12(a) of this chapter is grounds for—

(1) Denial of an application for a certificate or rating issued under this part for a period of up to 1 year after the date of that act; or

(2) Suspension or revocation of any certificate or rating issued under this part.

2. By adding a new § 61.16 to read as follows:

§ 61.16 Refusal to furnish test results.

(a) No person who refuses to furnish or authorize the release of the results of a test already taken, when requested by the Administrator in accordance with § 91.11 (c) or (d) of this chapter, is eligible for any certificate or rating under this part for a period of 1 year after the date of that refusal.

(b) A refusal to furnish or authorize the release of test results, when requested by the Administrator in accordance with § 91.11 (c) or (d) of this chapter, is grounds for suspension or revocation of any certificate or rating issued under this part.

PART 63—CERTIFICATION: CREWMEMBERS OTHER THAN PILOTS

3. By revising § 63.12 to read as follows:

§ 63.12 Offenses involving alcohol or drugs.

(a) A conviction for the violation of any Federal or state statute relating to the growing, processing, manufacture, sale, disposition, possession, transportation, or importation of narcotic drugs, marihuana, or depressant or stimulant drugs or substances is grounds for—

(1) Denial of an application for any certificate or rating issued under this part for a period of up to 1 year after the date of final conviction; or

(2) Suspension or revocation of any certificate or rating issued under this Part.

(b) The commission of an act prohibited by § 91.11(a) or § 91.12(a) of this chapter is grounds for—

(1) Denial of an application for a certificate or rating issued under this part for a period of up to 1 year after the date of that act; or

(2) Suspension or revocation of any certificate or rating issued under this part.

4. By adding a new § 63.12a to read as follows:

§ 63.12a Refusal to furnish test results.

(a) No person who refuses to furnish or authorize the release of the results of a test already taken, when requested by the Administrator in accordance with § 91.11 (c) or (d) of this chapter, is eligible for any certificate or rating under this Part for a period of 1 year after the date of that refusal.

(b) A refusal to furnish or authorize the release of test results, when requested by the Administrator in accordance with § 91.11 (c) or (d) of this chapter, is grounds for suspension or revocation of any certificate or rating issued under this part.

PART 65—CERTIFICATION: AIRMEN OTHER THAN FLIGHT CREWMEMBERS

5. By revising § 65.12 to read as follows:

§ 65.12 Offenses involving alcohol or drugs.

(a) A conviction for the violation of any Federal or state statute relating to the growing, processing, manufacture, sale, disposition, possession, transportation, or importation of narcotic drugs, marihuana, or

depressant or stimulant drugs or substances is grounds for—

(1) Denial of an application for any certificate or rating issued under this part for a period of up to 1 year after the date of final conviction; or

(2) Suspension or revocation of any certificate or rating issued under this part.

(b) The commission of an act prohibited by § 91.12(a) of this chapter is grounds for—

(1) Denial of an application for a certificate or rating issued under this part for a period of up to 1 year after the date of that act; or

(2) Suspension or revocation of any certificate or rating issued under this part.

PART 91—GENERAL OPERATING AND FLIGHT RULES

6. By revising § 91.11 to read as follows:

§ 91.11 Alcohol or drugs.

(a) No person may act or attempt to act as a crewmember of a civil aircraft—

(1) Within 8 hours after the consumption of any alcoholic beverage;

(2) While under the influence of alcohol;

(3) While using any drug that affects the person's faculties in any way contrary to safety; or

(4) While having .04 percent by weight or more alcohol in the blood.

(b) Except in an emergency, no pilot of a civil aircraft may allow a person who appears to be intoxicated or who demonstrates by manner or physical indications that the individual is under the influence of drugs (except a medical patient under proper care) to be carried in that aircraft.

(c) Whenever the Administrator has a reasonable basis to believe that a person may have violated paragraph (a)(1), (a)(2), or (a)(4) of this section, that person shall, upon request by the Administrator, furnish the Administrator, or authorize any clinic, hospital, doctor, or other person to release to the Administrator, the results of each test taken within 4 hours after acting or attempting to act as a crewmember that indicates percentage by weight of alcohol in the blood.

(d) Whenever the Administrator has a reasonable basis to believe that a

person may have violated paragraph (a)(3) of this section, that person shall, upon request by the Administrator, furnish the Administrator, or authorize any clinic, hospital, doctor, or other person to release to the Administrator, the results of each test taken within 4 hours after acting or attempting to act as a crewmember that indicates the presence of any drugs in the body.

(e) Any test information obtained by the Administrator under paragraph (c) or (d) of this section may be evaluated in determining a person's qualifications for any airman certificate or possible violations of this chapter and may be used as evidence in any legal proceeding under section 602, 609, or 901 of the Federal Aviation Act of 1958.

(Secs. 313(a), 601, 602, and 609 of the Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421, 1422, and 1429), and 49 U.S.C. 106(g) (Revised, Pub. L. 97-449; January 12, 1983))

Issued in Washington, D.C., on December 13, 1984.

Donald D. Engen,
Administrator.

[FR Doc. 85-9244 Filed 4-12-85; 4:05 pm]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 61, 63, and 91

[Docket No. 21956; Notice No. 81-9A]

Submission to Alcohol Tests

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: This notice supplements an FAA Notice of Proposed Rulemaking which, in part, proposed to require aircraft crewmembers to submit to a chemical test of the breath given by a representative of the Administrator under certain conditions. After further analysis, the FAA concluded that it is not practicable to have FAA employees conduct these tests. This notice proposes to require crewmembers to submit to tests for alcohol given by law enforcement officers under certain conditions. It is based, in part, on the National Transportation Safety Board (NTSB) determination that alcohol is a cause or factor in about 40 aircraft accidents annually, almost all of which are fatal. The proposed amendment would facilitate the enforcement of the present alcohol regulations. It is intended to reduce aircraft accidents and incidents attributed to consumption of alcoholic beverages.

DATE: Comments must be received on or before July 16, 1985.

ADDRESSES: Comments on this proposal may be mailed in duplicate to: Federal Aviation Administration; Office of the Chief Counsel; Attn: Rules Docket (AGC-204), Docket No. 21956; 800 Independence Avenue SW., Washington, D.C. 20591, or delivered in duplicate to: Room 916, 800 Independence Avenue SW., Washington, DC 20591. Comments delivered must be marked: Docket No. 21956. Comments may be inspected at Room 916 between 8:30 a.m. and 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Mike Sacrey or Roger Baker, Operations Branch (AFO-820), General Aviation and Commercial Division, Federal Aviation Administration, 800 Independence Avenue SW., Washington, D.C. 20591; Telephone (202) 426-8194.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rules by submitting such

written data, views, or arguments as they may desire. Comments relating to the environmental, energy, or economic impact that might result from adopting the proposals contained in this notice are invited. Communications should identify the regulatory docket or notice number and be submitted in duplicate to the address above. All communications received on or before the closing date for comments specified above will be considered by the Administrator before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket. Commenters wishing to have the FAA acknowledge receipt of comments submitted in response to this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments on Docket No. 21956." The postcard will be dated, time stamped, and returned to the commenter.

Availability of This Notice

Any person may obtain a copy of this notice of proposed rulemaking (NPRM) by submitting a request to the Federal Aviation Administration; Office of Public Affairs; Attention: Public Information Center, APA-430; 800 Independence Avenue SW., Washington, D.C. 20591, or by calling (202) 426-8058. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should request a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedures.

Background

Rules relating to the consumption of alcoholic beverages in connection with aircraft operations are set forth in § 91.11 of the Federal Aviation Regulations (FAR) (14 CFR 91.11). This section provides that no person may act as a crewmember of a civil aircraft within 8 hours after the consumption of any alcoholic beverage or while under the influence of alcohol. In addition, the FAA has adopted a rule, explained below, which prohibits acting as a crewmember of a civil aircraft while having a blood alcohol level of .04 percent or more by weight.

"Crewmember" is defined in FAR Part 1

as "a person assigned to perform duty in an aircraft during flight time." A pilot, flight engineer, flight navigator, or flight attendant is such a person.

The FAA is concerned about the serious hazard, during aircraft operations, resulting from impairment of the pilot's faculties due to alcohol. Even small amounts of alcohol affect judgment, coordination, performance, and reaction time. Although the FAA and aviation groups have expended a substantial amount of time and funds for a number of years trying to educate the flying public to this danger, the problem still remains. There continues to be a significant number of accidents each year where alcohol is found to be a factor or cause.

For example, according to an NTSB study, in 1979 general aviation aircraft were involved in 34 accidents where alcohol impairment was a cause/factor, 30 of which were fatal. This represents an 88 percent fatality rate for all of general aviation. Therefore, the FAA has taken additional steps to reduce the frequency of these accidents by strengthening the rules relating to the use of alcohol and drugs.

On July 27, 1981, the FAA published Notice of Proposed Rulemaking (NPRM) No. 81-9 (46 FR 38480), proposing regulations that were intended to deter persons from acting or attempting to act as a crewmember while under the influence of alcohol or drugs and to provide a basis for necessary enforcement action. Among other amendments, Notice 81-9 proposed to prohibit acting or attempting to act as a crewmember of a civil aircraft while having .04 percent or more alcohol in the blood.

Notice 81-9 also proposed to provide that a person whom the FAA had reason to believe had acted or attempted to act as a crewmember in violation of the alcohol rules, on request of the Administrator, would be required to submit to a chemical test of the breath.

Elsewhere in this Federal Register, the FAA is adopting a final rule disposing of the proposals in Notice 81-9, with the exception of the breath test. As proposed, the breath test would have been conducted by a representative of the Administrator on reasonable grounds to believe that the crewmember had violated § 91.11. After further consideration, it appears that it would be impracticable to have representatives of the Administrator equipped and trained to conduct the tests. As a number of commenters stated, due to staffing levels and the large geographic areas covered by district offices, FAA inspectors rarely are able to respond to

a report of a crewmember who is suspected of violating § 91.11 quickly enough to make a breath test useful. Breath testers would not be used often enough by FAA inspectors to warrant the expense of the testers and initial and recurrent training of the inspectors. There appears to be no practical method of requiring suspected violators to submit to a chemical test of the breath conducted by a representative of the Administrator. For this reason, the proposal requiring submission to a chemical test of the breath when requested by the Administrator and the consequences of refusal to submit to such a test were withdrawn.

The FAA recognizes, however, that chemical tests for alcohol content can be very useful in investigating alleged incidents involving alcohol. Many commenters note that state and local law enforcement officers have authority to conduct alcohol tests under their own laws or may arrange for others to conduct alcohol tests. The officers often are trained and equipped to recognize and handle people who may be under the influence of alcohol. The commenters also note that it is particularly important to obtain information on the pilot of an aircraft as soon as possible following an accident or incident and that state and local law enforcement officers often are at the scene hours before an FAA inspector can arrive. Many commenters suggest that the FAA take advantage of these officers' expertise and availability.

The FAA has determined that these comments have merit. Most law officers have the authority under state or local laws to conduct alcohol tests or to arrange for tests to be given. These officers have training in dealing with individuals who may be under the influence of alcohol and often are called to the scene of aircraft accidents or incidents. The FAA has, in the past, taken action against airmen for violating the alcohol rules based on information collected by state or local law enforcement officers pursuant to their own investigations, including observation of the airman or a chemical test to determine blood alcohol level.

The FAA does not currently require a crewmember to cooperate with such an investigation by a law enforcement officer. Under current rules, if the crewmember were to refuse to take a chemical test of the breath requested by a law officer who had reason to believe that the crewmember may have violated the FAA's alcohol rules, and if there was insufficient evidence to establish the violation without the test, the FAA could take no action against the

crewmember. Requiring crewmembers to submit to a test to determine the blood alcohol level, given by a state or local law enforcement officer, would be an effective method of obtaining additional evidence regarding suspected violations of the alcohol rules. The knowledge that such a test may be given also would act as a deterrent to individuals who wish to drink and fly.

The FAA expects that adopting a rule such as the one proposed in this notice would benefit the local communities whose law enforcement officers would be administering the breath tests. Both the FAA and these communities have an interest in protecting its citizens who use the airspace, as well as persons and property on the ground. During the comment period the FAA will seek comments and suggestions from a number of local police organizations. If the rule is adopted, the FAA will work closely with local police in a cooperative effort to ensure the effectiveness of the rule.

These proposed amendments are similar to those contained in Notice No. 81-9. However, since this rule would involve state and local communities, the FAA has determined this supplemental notice should be issued to afford these communities and other interested persons an opportunity to comment on these provisions.

Supplemental Proposal

The FAA proposes to require a crewmember of a civil aircraft to submit to testing to indicate the percentage by weight of alcohol in the blood, on the request of a law enforcement officer who is authorized under state or local law to conduct or otherwise obtain such a test, if there is a reasonable basis to believe that the crewmember may have violated the alcohol rules, including being under the influence of alcohol. The proposal also would make clear that failure to submit to the test could result in denial of a new certificate or a rating or suspension or revocation of a certificate or rating. In addition, a civil penalty action could be taken against the crewmember. Flight attendants, who do not hold airman certificates, would be subject to civil penalty action. The proposal would continue the new rule that crewmembers provide or release copies of medical test results which indicate blood alcohol levels.

The law officer conducting or obtaining the test would be acting under his or her own state or local authority. The Administrator does not propose to grant additional authority to state and local law enforcement officers. The proposed rule merely would require the crewmember to cooperate with an

otherwise lawful investigation by a law enforcement officer. This is similar to § 61.3(h) which, in part, requires a pilot to present his or her airman certificate for inspection upon request of a Federal, state, or local law enforcement officer.

The test could be a chemical test of the breath or any other test for alcohol conducted by the officer or by another person in accordance with the laws and procedures governing the officer. For instance, an officer might investigate an incident and come to the conclusion that a pilot may have operated an aircraft while under the influence of alcohol. Alternatively, an FAA inspector might observe a pilot to be apparently under the influence of alcohol and call this to the attention of an officer. The officer might then arrange for a breath test or blood test to be conducted pursuant to state or local law. The pilot, of course, would be (and currently is) subject to the state or local law regarding submission to the test. Under this proposal the pilot also would be required to submit to the test or face FAA Enforcement action.

In the past, the FAA generally has relied on observations by witnesses to enforce the alcohol rules. Witnesses have testified to indicia of alcohol observed in crewmembers such as stumbling, slurred speech, odor of alcohol, or difficulty with balance. The FAA has had success in such enforcement actions when the enforcement tribunal found the witnesses' testimony to be credible. The use of blood alcohol tests enable the FAA to take successful enforcement action in those cases in which witness observations alone may not provide sufficient evidence. The proposed rule would make blood alcohol tests more easily obtainable and would permit the FAA to take enforcement action against crewmembers who do not submit to a test under the conditions described. The FAA anticipates, however, that if the proposed rule were adopted, there would still be cases in which only witness observations were available and no blood alcohol tests were done. In such case, the FAA would proceed with enforcement action as it does now.

Economic Evaluation

The proposed rules would be enforcement tools. They would have no economic impact on crewmembers who are not suspected of failing to comply with the alcohol rules. The impact on those who would be requested to submit to an alcohol test would consist of a brief period of time spent undergoing the test.

A regulatory evaluation was prepared for Notice 81-9. The cost to the crewmember of complying with the proposal relating to breath tests would have been essentially the same as for the proposal contained in this supplemental notice. The regulatory evaluation for Notice 81-9 made the same conclusions regarding the economic impact as are made for this proposal.

Conclusion

Compliance with this proposal could impose only a minimal cost or economic burden on airmen. Accordingly, it has been determined that this is not a major regulation under Executive Order 12291. However, the proposal is significant under the Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 28, 1979). Since these proposals could have only a minor cost impact and would apply to individuals rather than small entities, I certify that under the criteria of the Regulatory Flexibility Act, these proposals, if adopted, would not have a significant economic impact on a substantial number of small entities. Because the cost of these proposals is so minimal, no regulatory evaluation has been prepared.

List of Subjects

14 CFR Part 61

Airmen, Aircraft pilots, Pilots, Alcohol and alcoholic beverages, Air safety, Safety, Aviation safety.

14 CFR Part 63

Airmen, Air safety, Safety, Aviation safety.

14 CFR Part 91

Aviation safety, Safety, Aircraft pilots, Liquor, Pilots.

The Proposed Rule

Accordingly, it is proposed to revise Parts 61, 63, and 91 of the Federal Aviation Regulations (14 CFR Parts 61, 63, and 91) as follows:

PART 61—CERTIFICATION: PILOTS AND FLIGHT INSTRUCTORS

1. By revising § 61.16 to read as follows:

§ 61.16 Refusal to submit to an alcohol test or to furnish test results.

(a) No person who refuses to submit to a test to indicate the percentage by weight of alcohol in the blood, when requested by a law enforcement officer in accordance with § 91.11(c) of this chapter, or who refuses to furnish or authorize the release of the results of a test already taken, when those results are requested by the Administrator in accordance with § 91.11 (c) or (d) of this chapter, is eligible for any certificate or rating under this Part for a period of 1 year after the date of that refusal.

(b) A refusal to submit to a test given by a law enforcement officer to indicate the percentage by weight of alcohol in the blood, when requested in accordance with § 91.11(c) of this chapter, or a refusal to furnish or authorize the release of test results, when requested by the Administrator in accordance with § 91.11 (c) or (d) of this chapter, is grounds for suspension or revocation of any certificate or rating issued under this Part.

PART 63—CERTIFICATION: CREWMEMBERS OTHER THAN PILOTS

2. By revising § 63.12a to read as follows:

§ 63.12a Refusal to submit to an alcohol test or to furnish test results.

(a) No person who refuses to submit to a test to indicate the percentage by weight of alcohol in the blood, when requested by a law enforcement officer in accordance with § 91.11(c) of this chapter, or who refuses to furnish or authorize the release of the results of a test already taken, when those results are requested by the Administrator in accordance with § 91.11 (c) or (d) of this chapter, is eligible for any certificate or

rating under this Part for a period of 1 year after the date of that refusal.

(b) A refusal to submit to a test given by a law enforcement officer to indicate the percentage by weight of alcohol in the blood, when requested in accordance with § 91.11(c) of this chapter, or a refusal to furnish or authorize the release of test results, when requested by the Administrator in accordance with § 91.11 (c) or (d) of this chapter, is grounds for suspension or revocation of any certificate or rating issued under this Part.

PART 91—GENERAL OPERATING AND FLIGHT RULES

3. By revising § 91.11(c) to read as follows:

§ 91.11 Alcohol or drugs.

(c) Whenever there is a reasonable basis to believe that a person who acted or attempted to act as a crewmember of a civil aircraft may have committed an act which is in violation of paragraph (a)(1), (a)(2), or (a)(4) of this section, that person shall do the following:

(1) On request of any law enforcement officer, submit to a test which the officer is authorized to obtain under state or local law to indicate the percentage by weight of alcohol in the blood.

(2) On request of the Administrator, furnish the Administrator, or authorize any clinic, hospital, doctor, or other person to release to the Administrator, the results of each test taken within 4 hours after acting or attempting to act as a crewmember that indicates percentage by weight of alcohol in the blood.

(Secs. 302, 313(a), 601, 602, and 609 of the Federal Aviation Act of 1958, as amended (49 U.S.C. 1342, 1354(a), 1421, 1422, and 1429), and 49 U.S.C. 106(g) (Revised, Pub. L. 97-449; January 12, 1983))

Issued in Washington, D.C., on December 13, 1984.

Donald D. Engin,

Administrator.

[FR Doc. 85-9243 Filed 4-12-85; 4:05 pm]

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April 17, 1985

Part V

Environmental Protection Agency

40 CFR Part 61

National Emission Standards for
Hazardous Air Pollutants; Standard for
Radon-222 Emissions From Underground
Uranium Mines; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 61

[AD-FRL-2814-7]

National Emission Standards for Hazardous Air Pollutants; Standard for Radon-222 Emissions from Underground Uranium Mines

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The U.S. District Court for the Northern District of California has ordered EPA to promulgate a final standard for airborne emissions of radionuclides from underground uranium mines by April 10, 1985, or to find that radionuclides are clearly not a hazardous air pollutant. This final rule is designed to limit exposure of the public to radon-222 emissions from underground uranium mines.

EFFECTIVE DATE: This final rule is effective on April 17, 1985. For existing sources, the standards shall not apply until 90 days after the effective date.

ADDRESSES: The rulemaking record is contained in Docket No. A-79-11. This docket is available for public inspection between 8:00 a.m. and 4:00 p.m., Monday through Friday, at EPA's Central Docket Section, West Tower Lobby, Gallery One, Waterside Mall, 401 M Street, SW., Washington, D.C. 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Paul J. Magno, Environmental Standards Branch (ANR-460), Criteria and Standards Division, Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, D.C. 20460, (703) 557-0704.

SUPPLEMENTARY INFORMATION:

I. Supporting Documents

A final Background Information Document has been prepared and single copies may be obtained by writing the Program Management Office, Office of Radiation Programs (ANR-458), U.S. Environmental Protection Agency, Washington, D.C. 20460, or by calling (703) 557-9351. Please refer to "Background Information Document: Standard for Radon-222 Emissions from Air from Underground Uranium Mines." This document contains a description of the uranium mining industry, projected exposures and risks to nearby individuals and to the general population, and descriptions of radon-222 control methods.

II. History of Uranium Mine Standard Development

On April 6, 1983, the Agency announced in the *Federal Register* a proposed standard to limit radon-222 emissions from underground uranium mines (48 FR 15076, April 6, 1983). This proposed standard was withdrawn by the Administrator in October 1984 on the basis that it did not meet the legal requirements of section 112 of the Clean Air Act (49 FR 43906, October 31, 1984). The Agency has also received additional technical information that suggested that bulkheads and other techniques to control radon-222 emissions may be feasible. The withdrawal action was taken in response to an order by the U.S. District Court for the Northern District of California compelling EPA, by October 23, 1984, to promulgate standards or make a finding that radionuclides are not a hazardous air pollutant within the context of section 112 of the Clean Air Act.

On December 11, 1984, the Court found the Administrator and the Agency in contempt of its previous order and directed the following remedial actions:

1. (a) Issue within 30 days of the date of the order final radionuclide emission standards for Department of Energy (DOE) facilities, Nuclear Regulatory Commission (NRC)-licensed and non-DOE Federal facilities, and elemental phosphorous plants, and

(b) Issue within 120 days of the date of the order final radionuclide emission standards for underground uranium mines; or

2. Make a finding based on the information presented at hearings during the rulemaking, that radionuclides are clearly not a hazardous air pollutant.

The Agency promulgated final standards for DOE facilities, NRC-licensed and non-DOE Federal facilities, and elemental phosphorous plants on January 17, 1985 (50 CFR 5190, February 6, 1985), although it is noted that the Agency intends to pursue its pending appeal of this portion of the District Court's order. A complete history of the events leading to this action is contained in the *Federal Register* notice announcing the final standards.

On February 21, 1985, EPA published in the *Federal Register* a proposed work practice standard to limit radon-222 emissions from underground uranium mines (50 FR 7280, February 21, 1985). The proposed work practice standard required bulkheading abandoned and temporarily abandoned mine areas to reduce the amount of radon-222 emitted to the above ground air from the mines. Following publication of the proposed standard, EPA conducted a public

hearing in Albuquerque, New Mexico, on February 27 and 28, 1985. The public record was held open until March 28, 1985, to allow for written comments to be received, however, EPA asked that comments be submitted as soon as possible to allow the Agency maximum time to consider them. A significant number of comments were received by the Agency on the last day of the public comment period. The short time between the submission of all the public comments and the Court deadline for promulgating the rule allowed the Agency a limited opportunity to respond to all of the comments. The Agency has generally reviewed all of the comments and is responding to the major issues and points in this notice. The Agency did not receive any comments or information subsequent to the public hearing that warranted a dramatic alteration in its approach. Changes made to the final rule in response to points raised in oral and written comments are discussed in the following sections.

III. Summary of the Final Rule

This rule is designed to limit exposure of the public to radon-222 emissions from underground uranium mines. The final rule differs in a number of ways from the proposed rule because of changes the Agency has made in response to public comments. This section provides an overview of the final rule; changes from the proposed rule are noted. The rationale for each of these changes is provided in the following sections of this notice. Both the *Federal Register* notice describing the proposed rule (50 FR 7280) and the Background Information Document provide further information on those portions of the final rule that have not changed from proposal.

The final rule:

(1) Applies to an owner or operator of an active underground uranium mine which has mined or will mine over 100,000 tons of ore during the life of the mine. A mine which will have or has had an annual ore production rate greater than 10,000 tons must also comply with the standard, unless it can be demonstrated that the mine will not exceed a cumulative ore production of 100,000 tons. (The proposed standard did not include the exclusion for mines producing greater than 10,000 tons of ore per year, but with an expected cumulative ore production of less than 100,000 tons.)

(2) Requires that an owner or operator of an underground uranium mine install and maintain bulkheads to isolate all abandoned and temporarily abandoned

areas of the mine. If a negative pressure behind the bulkhead is necessary, then a maximum of 20 percent of the total volume of air contained in the sealed area may be exhausted per day. A mine owner or operator may apply for an alternative standard, if necessary to protect miner health and safety. (The proposed standard did not provide a mine owner or operator the opportunity to seek an alternative standard based on miner health and safety.)

(3) Requires quarterly inspections of bulkheads and quarterly measurements of the air exhaust rate for those bulkheaded areas maintained under negative pressure. (The proposed standard required monthly bulkhead inspections and monthly measurements of the air exhaust rate.)

(4) Requires that any necessary repairs to bulkheads be made within ten days. (The proposed standard required that bulkhead repairs be made within three days.)

(5) Requires an annual certification of compliance with the standard. (The proposed standard required an annual report summarizing the number and volumes of abandoned and temporarily abandoned mine areas; the number of bulkheads maintained; and an estimate of the average amount of air in the bulkheaded areas which is exhausted per day.)

In establishing its final standard for radon-222 emissions from underground uranium mines, EPA had to weigh protection of the public health with protection of the mine personnel. The Agency believes that this standard will not significantly increase the radon decay product concentrations to which the underground miners are exposed. EPA intends to work with the Mine Safety and Health Administration to ensure that implementation of this standard will not jeopardize miner health and safety.

This final standard requires a work practice, i.e., bulkheading, which is commonly used throughout the uranium mining industry to direct fresh air to the working areas of the mine. However, the application of bulkheads to seal worked-out areas for reducing radon-222 emissions from underground mines has not been thoroughly tested. Because of the limited time allowed by the Court order, EPA was unable to completely evaluate bulkheading or other potentially applicable work practices. EPA intends, once this standard is promulgated, to begin long-term studies, as necessary, to evaluate the efficiency of bulkheads and other techniques for decreasing radon-222 emissions from underground uranium mines.

IV. Background Information

A. Industry Description

Uranium mining involves the handling of large quantities of ore containing uranium-238 and its decay products. The concentrations of these radionuclides in ore may be up to one thousand times greater than their concentration in other rocks and soils. Uranium mining is predominantly carried out by either surface (open pit) or underground mining methods, depending on the depth, ore grade, and thickness of the ore deposit. Underground uranium mines have generally accounted for about thirty to forty percent of the uranium oxide production in the United States.

The underground uranium mining industry has undergone substantial changes in recent years due to declining demand and competition from low-cost foreign sources. The total number of underground mines fell from a peak of 300 in 1980 to only six by March 1985. Currently, all underground uranium mining in the United States takes place in the western United States. In general, the mines presently operating are located in relatively remote areas of New Mexico, Colorado, Utah, and Arizona. Further reduction in the number of operating mines is expected during 1985.

Production of uranium oxide by underground mines peaked at 9600 tons in 1980; the industry estimates that uranium oxide production in 1985 will be approximately 1300 tons. EPA estimates that, based on Department of Energy projections of uranium oxide demand, the industry will produce close to 3100 tons of uranium oxide in 1985. The Agency has taken into account both its own and industry projections of uranium oxide production in assessing the risk associated with radon-222 emissions from underground uranium mines.

B. Radionuclide Emissions from Underground Uranium Mines

Radon-222 is the most significant radionuclide emitted to the above ground air from underground uranium mining activities. Radon-222 is released from underground mines in relatively high concentrations through mine ventilation systems. Results of measurement studies made at 27 large underground uranium mines during 1978-1979 showed that radon-222 emissions to air from individual mines ranged from 200 to 30,000 curies per year (Ci/y) with an average of 5600 Ci/y. These mines accounted for approximately 85 percent of the uranium oxide produced by all underground mines in 1978. Based on these

measurement results, the total radon-222 emissions from all underground uranium mines in 1978 were about 240,000 curies. EPA estimates emissions of radon-222 will be about 80,000 curies in 1985, based on DOE projections of uranium oxide demand. Using industry projections of uranium oxide production, emissions of radon-222 will be about 35,000 curies in 1985.

It is important to note that the rate of radon-222 emissions from underground uranium mines is highly variable, depending upon a number of interrelated factors, including mine ventilation rates, ore grade, exposed surface area, mining practices, and geologic formations. In addition, these mines can differ significantly in their configuration. The wide diversity among mines makes it difficult to predict emission rates of the effectiveness of emission reduction practices at any given mine.

C. Estimates of Exposure and Risk

The risk associated with emissions from underground uranium mines is primarily due to the short half-life decay products of radon-222. Radon-222 decays into a series of short-lived radionuclides. These decay products readily attach to dust particles that may become lodged in the lung when inhaled, thus irradiating the surrounding cells.

Individuals living near an underground uranium mine can be exposed to increased levels of radon decay products of a result of radon-222 being released from the mine ventilation shafts. Radon-222 contained in the outside atmosphere enters homes and other structures built near the mine exhaust vents through doors and windows, as well as other openings in the structure. The occupants of these structures may then be exposed to potentially harmful levels of radon-222 decay products.

The increased lifetime risk of fatal lung cancer to individuals living near large underground uranium mines from the mine emissions is estimated to range from about one in one thousand to one in one hundred. The potential exists for an increased risk as great as one in ten in some situations, e.g. a person living very close to several horizontal mine vents or in areas influenced by multiple mine emissions. EPA estimates the increase in the fatal cancer risk to the total population from radon-222 emissions from underground uranium mines to have been about one to four fatal cancer cases per year during the peak production period of 1978-1982. With the decrease in the number of operating underground uranium mines, the increased risk of fatal cancer is

expected to range from four-tenths to two fatal cancer cases per year during the period 1983-1990. Based on industry production projections, the increased risk of fatal cancer in 1985 is estimated to range from three-tenths to six-tenths of a fatal cancer case.

Exposure levels are derived from emission estimates, dispersion modelling, and population data. For any given emission rate, dispersion models predict concentrations at different distances from the emission source. By combining those estimated concentrations with census data on population densities, the number of people exposed at different concentrations can be estimated. However, several factors suggest that actual exposure levels to nearby individuals will be lower than those estimated. In estimating exposure, exposed individuals are assumed to be subjected to the emissions for 24 hours every day for 70 years (roughly a lifetime). This does not consider, for instance, the fact that most people in their daily routines move in and out of the specific areas where the concentrations are the highest. In the case of underground uranium mines, the average life of a mine ranges from 10-20 years, although some mines have operated for almost thirty years.

Several commenters expressed concern about the Agency's risk estimates and the need for regulation of this source category. Three specific points were addressed: (1) The risk from radon-222 emissions from underground uranium mines is not of the magnitude necessary to warrant regulation under section 112 of the Clean Air Act, therefore, the Agency should "delist" radionuclides from regulatory consideration under section 112; (2) little evidence exists to indicate health effects result below total exposure levels of one hundred working level months; and (3) the decline in the uranium mining industry significantly deflates the already overestimated health risks presented by the Agency.

The Agency has considered these interrelated issues and has concluded that the "listing" of radionuclides as a hazardous air pollutant within the context of section 112 of the Clean Air Act was entirely appropriate. Section 112 of the Clean Air Act requires the Administrator to review all available relevant information and determine whether emissions of radioactive pollutants to the ambient air will cause, or contribute to, air pollution which may reasonably be anticipated to endanger public health. If the Administrator concludes that emissions of

radionuclides meets this criterion, he must list and regulate radionuclides under section 108(a)(1), section 111(b)(1)(A), or, if he finds that radionuclide emissions cause, or contribute to, air pollution which may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness, section 112(b)(1)(A) of the Act, or take any combination of such actions.

The Agency believes that emission of radionuclides from underground uranium mines meets the general criterion for an affirmative finding under section 122. Further, the Agency believes that emissions of radionuclides from underground uranium mines meet the criterion for regulation under section 112 of the Act. Specifically, there is no doubt that radionuclides are carcinogenic, mutagenic, and teratogenic. This conclusion is based on extensive scientific evidence derived from studies of both human and animal populations. Underground uranium mines emit radon-222 and its decay products in large quantities. Many studies in the United States and other countries of miners exposed to radon-222 gas and its decay products have presented highly convincing evidence that exposure to these radionuclides causes or contributes to lung cancer.

Estimating the magnitude of the increased risk of developing lung cancer to individuals living near underground uranium mines and to the general population living downwind of the mines is complicated and uncertain. Epidemiological data exist that demonstrate a relationship between cumulative exposure to radon-222 decay products and increased lung cancer risk. There is substantial evidence that relates cumulative exposure of greater than approximately one hundred working level months (WLM) to an increased risk of lung cancer. While some studies based on human data indicate that exposure to less than one hundred WLM increases the risk of lung cancer, these data are less conclusive. There are considerable difficulties in demonstrating increased risk at a statistical confidence level of 95 percent for exposure at relatively low concentrations of radon-222 decay products because a very large study population is needed. It is often difficult to identify appropriate study populations large enough to conduct such studies to examine risks at very low levels.

Cumulative exposure to a person living near an underground uranium mine due to mine emissions is not likely to

exceed twenty WLM over his lifetime. (This assumes exposure to about 0.3 WLM per year for about 70 years.) While this is considerably below cumulative exposures at which we have substantial human evidence relating to lung cancer, the Agency believes that such exposure is not below a threshold at which no significant health damage could occur. Radiation protection organizations, national authorities, and prestigious scientific committees worldwide use the assumption that there is no threshold below which exposure to radiation does not pose some risk to health. For example, the National Academy of Sciences' Committee on Biological Effects of Ionizing Radiation recommended that health risks from low level exposures to alpha radiation, such as that produced by radon-222 decay products, be estimated by extrapolating risks from higher exposures using a linear nonthreshold model. Therefore, extrapolations from the available miner epidemiological data have been used by EPA to estimate risk at exposure levels caused by radon-222 emissions from underground uranium mines.

Section 112 requires not only a finding that the pollutant at issue is hazardous in the abstract, but also that it poses a public health risk in its form as an air pollutant. By coupling information on radon-222 emissions from mines, air transport models, and health risk models, the Agency estimates that the increased lifetime risk to individuals living near an underground uranium mine could be about one chance in one hundred of incurring lung cancer because of the emissions. For perspective, the current average lifetime risk of developing lung cancer in the United States is about three in one hundred. Clearly, radon-222 emissions from underground uranium mines may significantly affect a nearby individual's lung cancer risk. In addition, several fatal cancers per year may result in the total population due to these emissions, depending on the quantity of ore production each year.

In making its health risk estimates, EPA evaluated the air pollution risk of radon-222 emissions from underground uranium mines based on the magnitude of both current and potential emissions, on observed and estimated ambient radon-222 concentrations, on the proximity of large populations to emitting sources, on estimates of health risk to exposed populations, and on considerations of uncertainties associated with risk estimates. The assessments and the assumptions used to estimate lifetime risks are described

in more detail in the Background Information Document. In addition, a study conducted during the period 1978-1980 by the New Mexico Environmental Improvement Division clearly demonstrated elevated concentrations of radon-222 in air near underground uranium mines in the Ambrosia Lake area of New Mexico.

The Agency believes that there is sufficient evidence to conclude that potential increases in the risk of lung cancer to individuals and the general population due to radon-222 emissions from underground uranium mines may be anticipated to endanger public health and may be anticipated to result in an increase in mortality. Consequently, regulation of this source category under sections 122 and 112 is appropriate.

The Agency also believes that a standard limiting exposure of the public to radon-222 emissions from underground uranium mines is warranted, despite the low number of operating mines. The Congress intended in section 112 that EPA act by a date certain to protect the health of current and future generations from emissions of pollutants that it determined to be hazardous. This is still the Agency's responsibility even if, as some might argue, current production levels have reduced risk. Demand for uranium oxide may increase. In the peak production years, the increase in an individual's lifetime risk of lung cancer from radon-222 emissions from underground uranium mines may have been as high as one in ten to those individuals exposed to multiple mine vents and increased population risk may have been as high as four fatal cancers per year. Without a standard such as this, risks to the public, both nationally and regionally, would increase if demand and production of uranium oxide increases.

Section 122 of the Clean Air Act allows EPA to use section 108(a)(1) or section 111(b)(1)(A) in combination with section 112 if the Administrator determines it to be suitable. At this time, the Agency has chosen to regulate radon-222 emissions from underground uranium mines only under section 112. Current information suggests that regulation under these other sections would not significantly improve control of radon-222 emissions from underground uranium mines. Should new information alter this conclusion, the Agency may reconsider its approach to regulating underground uranium mines.

D. Control Technology

Since radon-222 is a noble gas and the volume of air discharged through mine

vents is very large, at present there is no practical method to remove radon-222 from the mine exhaust air. Application of conventional methods to remove radon-222 from mine ventilation air at the volumes of air which must be treated would require large, complex, unproven systems that would be extremely costly, i.e., adding at least \$18 to \$44 to the total cost of producing a pound of uranium oxide. (Currently, the average cost to produce one pound of uranium oxide from an underground mine is about \$35.) The industry now employs a number of practices to reduce radon decay product concentrations in the mine to meet occupational exposure standards established by the Mine Safety and Health Administration. These practices, which include bulkheading abandoned areas of the mine, have the effect of reducing radon-222 emissions to the above ground air.

At EPA's request, the U.S. Bureau of Mines evaluated the cost and effectiveness of various work practices in reducing radon-222 emissions. The results of the study suggested that bulkheading could reduce emissions of radon-222 by about 10 to 60 percent. Based on the peak production year, the amount of population risk reduction achieved could range from two-tenths to two fatal cancer cases per year. Estimates for 1983, the most recent year for which actual production data are available, range from one-tenth to one fatal case per year. In 1985, based on industry production projections, the amount of population risk reduction is estimated to range from three-hundredths to three-tenths of a fatal cancer case per year. These are only rough estimates based on installing bulkheads in a presently uncontrolled mine (i.e., a mine with no bulkheads).

Information presented during the public comment period indicates that uncertainty exists as to the amount of radon-222 emission reduction achievable by bulkheading in existing mines. This is in part due to the complexity in the configuration of these mines, past mining practices, and consideration of miner health and safety. The extent to which additional bulkheads can be installed to further reduce radon-222 emissions can only be determined on a case-by-case basis.

Comments from the industry supported EPA's conclusion that bulkheading is the only practical work practice that could be used to reduce radon-222 emissions to the above ground air. Other methods, such as rock sealants and backfilling, may also reduce radon-222 emissions; however, they are not thought to be as cost-effective or practical as bulkheading.

After considering all the available information on control technologies, the Agency has concluded that bulkheading abandoned and temporarily abandoned mine areas to seal the radon-222 underground is a practical method of reducing radon-222 emissions from the mines to the above ground air.

E. Bulkheading

Bulkheads are air-restraining barriers used to direct air and prevent contamination or leakage of fresh air going to the active areas of the mine. This practice reduces the radon-222 and decay product concentrations in the active areas of the mine and also reduces the volumes of air needed to ventilate the mine. Bulkheading practices vary among mines; some mines make extensive use of bulkheads, while others use few bulkheads.

A secondary benefit of bulkheading inactive areas of a mine is that radon-222 emanating from the rock surface will decay in the isolated area. Hence, this technique can also reduce radon-222 emissions to the above ground air. The amount of emission reduction achieved is dependent on the volume of inactive areas that are sealed with bulkheads and the amount of air removed from these areas.

The radon-222 in the sealed area behind a bulkhead will build up to relatively high concentrations (i.e., tens of thousands of picocuries per liter), so it is necessary to prevent or minimize any leakage of air from behind the bulkhead into the working areas of the mine. Any such leakage could significantly increase the radon decay product concentration to which the miners are exposed. Therefore, it is often necessary to maintain a negative differential pressure behind the bulkhead to prevent leakage of contaminated air into the active mine airways. This negative pressure is achieved by bleeding (i.e., removing) air from behind the bulkhead into an exhaust airway. For bulkheads to be effective in reducing radon-222 emissions to above ground air, however, the amount of air bleed necessary to maintain an adequate pressure differential across the bulkhead must be minimized. The smaller the air bleed, the more radon-222 will decay behind the bulkhead rather than being released above ground.

V. The Final Standard

The complexity in the structure of underground uranium mines, the uncertainties in the effectiveness of in-mine control techniques, and the lack of suitable control technology to capture

radon-222 being vented from the mines cause the Agency to conclude that an emission standard is not feasible. The effectiveness of techniques for radon-222 emission reduction is not known. This means that predictable, hence measurable, steps toward compliance with a generic emission standard can not be identified. In this instance, section 112(e)(1) of the Clean Air Act allows the Agency to prescribe a work practice or other type standard to control the pollutant. This standard, therefore, requires that bulkheading be used to reduce emissions of radon-222 from the mines. A more thorough description of the individual components of the standard and the rationale follows.

A. Applicability

The standard is applicable to an owner or operator of an active underground uranium mine which has mined or will mine over 100,000 tons of ore during the life of the mine. Mines which have had or will have an annual ore production rate greater than 10,000 tons must also comply with the standard, unless it can be demonstrated that the mine will not exceed a cumulative ore production of 100,000 tons.

An evaluation of radon-222 emissions from underground mines operating in 1978 as a function of cumulative ore production showed that 188 mines or 75 percent of all the mines had a cumulative ore production of less than 100,000 tons. The estimated radon-222 emission rate from each of these mines was less than 200 curies per year, and as a group they contributed only five percent of the total curies emitted by all underground uranium mines in 1978. Since the radon-222 emissions from underground uranium mines with cumulative ore productions of less than 100,000 tons are small, the Agency has concluded that these mines need not be covered by the standard.

One commenter suggested that the Agency eliminate the 100,000 tons of cumulative ore production criterion; another suggested increasing it to 500,000 tons. The Agency has decided to maintain the cutoff at 100,000 tons cumulative ore production in order to include older mines which are likely to have significant emissions of radon-222 due to the large amount of surface area emanating from this radionuclide. EPA chose the 100,000 tons cutoff based on the results of the study discussed previously. Ninety-five percent of the radon-222 emissions from underground uranium mines in 1978 were from mines with a cumulative ore production of 100,000 tons or greater.

The annual ore production value of 10,000 tons was selected to ensure that mines which are likely to exceed 100,000 tons of cumulative ore production will be covered by the standard on the effective date of the standard or at the time a new mine begins production. Evidence exists which indicates that mines with an annual ore production rate of 10,000 tons or greater are likely to mine 100,000 tons of ore during their lifetime. The standard allows a mine owner or operator to demonstrate that the mine will not exceed 100,000 tons of cumulative ore production, and, thus, not be subject to the standard.

B. Bulkheading Requirements

Comments generally agreed with the Agency's conclusion that bulkheading is a practical method to reduce radon-222 emissions to the above ground air from underground uranium mines. One commenter suggested that backfilling abandoned areas with mill tailings might also yield some reduction in radon-222 emissions. This final rule, while prescribing bulkheading requirements, allows a mine owner or operator the flexibility to use other methods of radon-222 control, such as backfilling, upon approval by the Administrator.

The standard requires that an owner or operator of an underground uranium mine install and maintain reliable bulkheads to isolate all abandoned and temporarily abandoned areas of the mine. If a negative pressure behind the bulkhead is necessary, then a maximum of 20 percent of the total volume of air contained in the sealed area may be exhausted per day. Many commenters expressed concern about limiting the amount of air which can be drawn from behind a bulkhead to achieve a negative pressure. In some situations, this practice may result in an increase in radon-222 decay product concentrations in the working areas of the mine. In addition, it may be difficult or impractical to measure the amount of air removed from a bulkheaded area. Commenters requested that EPA eliminate the limitation on the amount of air which can be drawn from behind a bulkhead.

EPA does not intend to promulgate a standard which increases miner exposure to radon decay products. However, a limit on the rate of removal of air from behind a bulkhead is necessary to provide sufficient residence time for the radon-222 in the isolated area to decay. A 20 percent per day value was selected as a balance between the need to minimize the rate of air removed from the isolated area and the need to maintain adequate

negative pressure to prevent radon-222 from leaking into active mine airways and increasing the radon-222 decay product exposure to the miners. Our analysis estimates that, when the exhaust rate is maintained at 20 percent, approximately 50 percent of the radon-222 trapped behind the bulkhead will decay and thus will not be vented to the above ground air. Reducing the air exhaust rate to 10 percent per day would result in a radon-222 reduction of approximately 85 percent, but we do not have enough information at the present time to know if this will provide adequate protection of the miners.

Industry representatives explained to EPA that the ventilation routes in many existing mines are designed so that air from active areas is exhausted through the inactive areas of the mine. As fresh air is brought into the mine, care is taken to prevent its contamination with radon-222 decay products prior to its reaching the active work areas. Bulkheads are constructed primarily to seal unused portions of the mine adjacent to the intake airways to prevent fresh air from escaping or becoming contaminated. In current practice, the mined-out areas become exhaust airways as the mining process retreats towards intake airways. Therefore, a major portion of the mined-out areas must be kept open to allow passage of air to the exhaust vents. In the case of one mine, ninety-six percent of the mine is inactive areas which serve as exhaust routes for contaminated air. Bulkheading is unlikely to be practical in these inactive areas unless major changes are made in the ventilation schemes of the mines, such as constructing new ventilation shafts. In addition, entering these areas to construct bulkheads may jeopardize the health and safety of the miners because of high concentrations of radon-222 decay products and ground instability. Commenters requested that EPA exempt from the requirements of the standard inaccessible areas and those areas which serve as ventilation passageways.

After hearing the comments discussed above and reviewing the configurations of several existing mines, the Agency has decided to include a provision in the standard to allow mine owners or operators to apply for an alternative standard, if necessary to protect miner health and safety. By including this option, rather than simply eliminating the air exhaust rate limitation and exempting certain areas of a mine based on their function, the Agency hopes to provide incentive to design new mines in such a way as to limit radon-222 emissions to above ground air. Industry

representatives acknowledged at the public hearing that a new mine could be designed to limit the number of inactive areas used as exhaust routes and to maximize the amount of area which could be bulkheaded.

C. Reporting and Recordkeeping

The Agency received numerous comments on the reporting and recordkeeping requirements of the proposed rule. In an effort to minimize the amount of additional time personnel must spend in a mine to meet its standard, EPA has decreased the number and frequency of the reporting and recordkeeping requirements imposed by the final rule. The revisions are as follows:

(1) *Inspections* The frequency of inspections of bulkhead conditions and measurements of the air exhaust rate for those bulkheaded areas maintained under negative pressure has been reduced from monthly to quarterly. Records of these inspections must be kept at the mine and be available for review by EPA.

(2) *Bulkhead repairs* The length of time allowed to make necessary repairs to bulkheads has been lengthened from three days to ten days. This change allows mine operators greater flexibility in managing their work force.

(3) *Annual report* The amount of information that is required to be submitted annually to EPA has been reduced. A mine owner or operator must submit an annual certification of compliance with the final rule. Records of the number and volumes of abandoned and temporarily abandoned areas, the number of bulkheads maintained, and an estimate of the average amount of air in the bulkheaded areas which is exhausted per day must be kept at the mine. Annual submission of this information was required in the proposed rule.

D. Definitions

Based on public comments, several definitions were modified in the final rule.

(1) The definitions of "abandoned mine area" and "temporarily abandoned mine area" have been modified to exempt not only those areas which function as escapeways, but also areas formerly used as lunchrooms, shops, and transformer or pumping stations. These areas have been exempted because they are nonproduction areas which have low radon-222 emanation rates. In addition, the exemption for ventilation passageways is now limited to ventilation passageways designed to minimize the distance to vents and no longer allows large mined-out areas to

function as ventilation passageways. Exempting these areas from the bulkheading requirements would limit the amount of radon-222 emission reduction achieved by the standard. In particular, the Agency wants to ensure that new mines are designed to avoid this practice.

(2) The definition of "active mine" has been modified to include only those mines in which ore or waste material are currently removed by conventional methods. This change was made to exempt slope leaching which does not require workers to enter the mine, except in rare instances.

(3) A definition of "work" has been added to clarify the intent of the standard. For the purposes of the standard, "work" means mining activity done in the usual and ordinary course of developing and operating an underground uranium mine.

VI. Effects of the Final Standard

The deadline imposed by the District Court requires the Agency to promulgate a standard for underground uranium mines based only on the currently available technical information. An accurate estimate of the radon-222 emission reduction achieved by the standard cannot be made with existing information. The bulkheading requirements of the rule are expected to result in a decline in individual and population risks as emissions of radon-222 are reduced. Though the maximum individual risk in particular has not been reduced to levels EPA has selected in other standards, the very short time available for developing this rule, and the possibility that any reduction in risk to the general population might be achievable only by increasing the risk to miners, make it impossible to impose further controls at this time. EPA will continue to investigate this matter to determine the possibility of tightening controls in the future. Since most mines already install bulkheads to reduce ventilation requirements, it is not possible to estimate the incremental radon-222 emission reduction achieved by the standard. EPA intends to gather additional information on the extent and nature of existing bulkheading practices and the efficacy of the standards.

Further, the cost of the standard can only be generally estimated. Because we do not know the extent of present bulkheading practices or what additional bulkheading is practical, we cannot precisely estimate the cost to meet this standard. Limited modelling analysis shows that the cost of installing bulkheads ranges from about one to five cents per pound of uranium oxide produced. Based on the peak production

year, the total cost to the industry could range from \$200,000 to \$1,000,000 per year. Cost to the total industry in the first year is estimated to range from \$30,000 to \$150,000. Even if these costs are significantly underestimated for some mines, it is highly unlikely that the cost of the standard would exceed one percent of the cost of producing uranium oxide.

EPA intends to begin long-term studies, as necessary, to more thoroughly determine the efficiency and cost of bulkheads and other techniques for decreasing radon-222 emissions to the above ground air from underground uranium mines. Such a study would examine ways to reduce air emissions further without increasing potential exposure to miners. The results of a study may lead to some modification of the Agency's standard.

VII. Miscellaneous

A. Docket

The docket is an organized and complete file of all information considered by EPA in the development of this standard. The docket allows interested persons to identify and locate documents so they can effectively participate in the rulemaking process. It also serves as the record for judicial review. Transcripts of the hearings, all written statements, and other relevant documents are placed in the docket and are available for inspection and copying during normal working hours.

B. General Provisions

The general provisions of 40 CFR Part 61, subpart A apply to all sources regulated by this rule.

C. State Implementation and Enforcement of Emission Standards

D. Communications

Communications with the Administrator regarding the reporting and recordkeeping requirements of this rule, as well as requests for waivers, shall follow the provisions of § 61.10, except as otherwise noted in this rule.

E. Executive Order 12291

Under Executive Order 12291, issued February 17, 1981, EPA must judge whether a rule is a "major rule" and, therefore, requires that a Regulatory Impact Analysis be prepared. EPA has determined that this rule is not a major rule as defined in section 1(b) of the Executive Order because the annual effect of the rule on the economy will be less than \$100 million. Also, it will not cause a major increase in costs or prices for any sector of the economy or for any

geographic region. Further, it will not result in any significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States enterprises to compete with foreign enterprises in domestic or foreign markets. Under Executive Order 12291, this rule was submitted to the Office of Management and Budget (OMB) for review. Any written comments from OMB to EPA, and responses to those comments, are included in the docket.

F. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved by OMB under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* and have been assigned OMB control number 2060-0115.

G. Regulatory Flexibility Analysis

Section 603 of the Regulatory Flexibility Act, 5 U.S.C. 603, requires EPA to prepare and make available for comment an "initial regulatory flexibility analysis" in connection with any rulemaking for which there is a statutory requirement that a general notice of proposed rulemaking be published. The "initial regulatory analysis" describes the effect of the proposed rule on small business entities.

However, section 604(b) of the Regulatory Flexibility Act provides that section 603 "shall not apply to any proposed . . . rule if the head of the Agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities."

EPA believes this final rule will have little or no impact on small business because the total costs associated with the standard will have relatively little impact on the total cost of producing uranium oxide. In addition, the standard will apply only to large, operating underground uranium mines.

For the preceding reasons, I certify that this rule, will not have significant economic impact on a substantial number of small entities.

H. Judicial Review

Judicial review of these standards is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit within 60 days of today's publication date. The requirements established in this notice may not be challenged later in civil or criminal proceedings brought by EPA to enforce them.

List of Subjects in 40 CFR Part 61

Air pollution control, Hazardous materials, Asbestos, Beryllium, Mercury, Vinyl chloride, Benzene, Arsenic, Radionuclides.

Dated: April 10, 1985.

Lee M. Thomas,
Administrator.

Part 61 of Chapter 1 of Title 40 of the Code of Federal Regulations is amended by adding the following Subpart B consisting of §§ 61.20 through 61.28:

PART 61—[AMENDED]

Subpart B—National Emission Standard for Radon-222 Emissions from Underground Uranium Mines

Sec.

- 61.20 Applicability.
- 61.21 Definitions.
- 61.22 Standard.
- 61.23 Alternatives Standard.
- 61.24 Bulkhead Inspection and Testing.
- 61.25 Bulkhead Repair.
- 61.26 Recordkeeping.
- 61.27 Reporting Requirements.
- 61.28 Source Reporting and Waiver Request.

Authority: Sec. 112 and 301(a) Clean Air Act, as amended, 42 U.S.C. 7412, 7601(a).

Subpart B—National Emission Standard for Radon-222 Emissions from Underground Uranium Mines

§ 61.20 Applicability.

The provisions of this subpart are applicable to an owner or operator of an active underground uranium mine which:

- (a) Has mined or will mine over 100,000 tons of ore during the life of the mine; or
- (b) Has had or will have an annual ore production rate greater than 10,000 tons, unless it can be demonstrated that the mine will not exceed a total ore production of 100,000 tons during the life of the mine.

§ 61.21 Definitions.

As used in this subpart, all terms not defined here shall have the meaning given them in the Clean Air Act or in subpart A of Part 61 and the following terms shall have the specific meanings given below:

- (a) "Abandoned area" means a deserted mine area in which work has ceased and in which further work is not intended. Areas which function as escapeways, and areas formerly-used as lunchrooms, shops, and transformer or pumping stations are not considered abandoned areas. Except for designated ventilation passageways designed to minimize the distance to vents, worked-out mine areas are considered

abandoned areas for the purpose of this subpart.

(b) "Active mine" means an underground uranium mine from which ore or waste material is currently removed by conventional methods.

(c) "Area" means a man-made underground void from which ore or waste has been removed.

(d) "Bulkhead" means an air-restraining barrier constructed for long-term control of radon-222 and radon-222 decay product levels in mine air.

(e) "Inactive mine" is a mine from which uranium ore has been previously removed but which is not an active mine as of the effective date of the standard. Inactive mines which become active mines after the effective date of the standard are considered new sources under the provisions of subparts A and B of this part.

(f) "Modification" as applied to an active underground uranium mine means any major change in the method of operation or mining procedure which will result in an increase in the amount of radon-222 emitted to air. The normal development or operation of an active mine, even though it results in an increase in emissions, is not considered a modification for the purposes of this subpart.

(g) "Temporarily abandoned area" means a mine area in which further work is not intended for at least six months. Areas which function as escapeways, formerly-used lunchrooms, shops, and transformer or pumping stations are not considered abandoned areas. Except for designated ventilation passageways designed to minimize the distance to vents, worked-out mine areas are considered temporarily abandoned areas for the purpose of this subpart if work is not intended in the area for at least six months.

(h) "Underground uranium mine" means a man-made underground excavation made for the purpose of removing material containing uranium for the principal purpose of recovering uranium.

(i) "Work" means mining activity done in the usual and ordinary course of developing and operating a mine.

§ 61.22 Standard.

(a) An owner or operator of an underground uranium mine subject to this subpart shall install and maintain bulkheads to isolate all abandoned and temporarily abandoned areas according to the following requirements:

- (1) The bulkhead shall be a structure designed and constructed for long-term control of the isolated area and shall be sealed to minimize air leakage through

the bulkhead. The bulkhead shall be of sufficient structural strength to resist mechanical abuse, blasting shocks, air pressure differentials, and rock movement for an extended period of time in the mine-operating environment. The basic bulkhead structure may consist of a timber or metal stud frame, covered with lumber, expanded metal lath, plywood, or other sheet products. It may be a continuous nonporous membrane or it may support such a membrane. A sealant shall be applied onto the basic structure and in the joints between the structure and the rock to form a continuous seal and radon barrier. The sealant shall be of a type that will provide a protective seal, and will not easily crack or develop holes or leaks. A sealant may consist of coatings of mortar, masonry, latex, urethane foam, or similar materials. A properly constructed and sealed bulkhead shall have no visible cracks or gaps.

(2) If negative pressure behind the bulkhead is used, then a maximum of 20 percent of the total volume of air contained in the isolated area can be exhausted per day.

(3) As mine areas become abandoned or temporarily abandoned after the applicable date of this standard, the mine owner or operator must install a bulkhead in compliance with the provisions of § 61.22(a) within 30 days of the area becoming abandoned or temporarily abandoned.

(b) Upon written application from an owner or operator of an underground uranium mine subject to this subpart, the Administrator may approve alternative bulkhead designs or construction, or other methods for isolating abandoned or temporarily abandoned areas, if such alternatives can be shown to provide isolation of the area equivalent to the requirements of § 61.22(a)(1).

§ 61.23 Alternative Standard.

(a) If compliance with the requirements of § 61.22 will result in increased radon-222 decay product concentrations in the active areas of the mine, will require workers to enter unsafe areas, or will otherwise be impractical to achieve because of unique or unusual circumstances, then the owner or operator of an existing source (i.e., existing active mine) may apply to the Administrator for an alternative standard. The Administrator may establish an alternative standard if the applicant demonstrates that an alternative is necessary to provide for the health and safety of the workers and will minimize the exposure of nearby individuals and the general population to radon-222 decay products, to the

extent practical. Applications for an alternative standard shall be made within 90 days of the effective date of the standard and include the following information:

(1) The reasons for requesting an alternative;

(2) A description of the alternative requested;

(3) A description of all measures that have been taken or will be taken by the mine owner or operator to minimize the exposure of nearby individuals and the general population to radon-222 decay products, to the extent practical.

(4) A schedule for complying with the alternative standard.

(b) An inactive mine which again becomes active may request an alternative standard under § 61.23(a). Application for an alternative standard must be submitted as part of an application for approval of construction or modification as required under § 61.07.

(c) Requests for an alternative standard shall be sent to the Assistant Administrator for Air and Radiation (ANR-443), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460.

§ 61.24 Bulkhead Inspection and Testing.

An owner or operator of an underground mine subject to the requirements of § 61.22 shall conduct the following bulkhead inspections and tests:

(a) A visual inspection of the condition of each bulkhead required under § 61.22(a) shall be conducted every three months by a qualified representative of the mine owner or operator to determine if, in his or her judgment, the integrity of the bulkhead is in compliance with the requirements of § 61.22(a)(1). A record of each inspection shall be made in accordance with the requirements of § 61.26.

(b) For bulkheaded areas maintained under negative pressure, measurement of the air exhaust rate from the area shall be made at least every three months to determine compliance with the requirement of § 61.22(a)(2). A record of each exhaust rate measurement shall be made in accordance with the requirements of § 61.26.

(c) Upon written application from an owner or operator of an underground uranium mine subject to this subpart, the Administrator may approve alternative testing and inspection procedures if such alternative procedures can be shown to provide reasonable assurance that the mine is in compliance with the requirements of § 61.22(a).

§ 61.25 Bulkhead Repair.

Bulkheads determined not to be in compliance with the requirements of § 61.22(a) during inspections required under § 61.24 shall be repaired within ten days in accordance with the requirements of § 61.22(a).

§ 61.26 Recordkeeping.

Records of inspections and tests required under § 61.24 shall be maintained as described below. These records shall include a bulkhead identification number and location and the date of each inspection or test.

(a) The results of each inspection required under § 61.24(a) shall be recorded as follows:

(1) A description of the condition of the bulkhead including identification of any damage and the extent of damages.

(2) A determination that the bulkhead is in compliance with the specifications of § 61.22(a) or that repairs are needed.

(b) A record shall be maintained for each bulkhead repaired under the requirements of § 61.25.

(c) A record shall be maintained for each air flow rate measurement conducted under the requirements of § 61.24(b). These records shall show the results of each test and the method used. The percent of the total air volume behind the bulkheaded area which is exhausted per day at the measured flow rate shall be recorded.

(d) Records of inspections and tests shall be maintained at the mine and made available for inspection and copying by the Administrator for a minimum of two years.

(e) A current map or schematic of the mine showing the location of each bulkhead required under § 61.22(a) and the approximate air volume of the isolated area shall be maintained. Each bulkhead shall be assigned an identification number which shall be used in inspections and tests, and the reporting requirements of §§ 61.24 and 61.26. This map shall be kept at the mine and be made available for review by the Administrator.

(Approved by the Office of Management and Budget under the control number 2060-0115)

§ 61.27 Reporting Requirements.

(a) An owner or operator of an underground uranium mine subject to the requirements of this subpart shall submit a certification to the Administrator by March 1, 1986, and annually thereafter. This certification shall be based on information and data concerning the calendar year immediately preceding the required data for submission of the certification and shall consist of a statement that the

bulkheading requirements of § 61.22(a) or any alternative standard established under § 61.23 have been implemented.

(b) If a waiver of compliance is granted, this certification is to be submitted on a date scheduled by the Administrator.

(Approved by the Office of Management and Budget under control number 2060-0115)

§ 61.28 Source Reporting and Waiver Request.

(a) The owner or operator of any existing source, or any new source to which a standard prescribed under this subpart is applicable which had an initial startup which preceded the effective date of a standard prescribed under this subpart shall, within 90 days after the effective date, provide the following information in writing to the Administrator:

- (1) Name and address of the owner or operator;
- (2) The location of the source;

(3) A brief description of the nature, size, design, and method of operation of the mine including: (i) current or expected annual ore production rates, (ii) current cumulative ore production, (iii) expected cumulative ore production over the life of mine;

(4) The number of abandoned and temporarily abandoned areas in the mine and the number of these areas which are isolated by bulkheads; and

(5) A statement by the owner or operator of the source as to whether he can comply with the standard prescribed in this subpart within 90 days of the effective date.

(b) An owner or operator of an existing underground uranium mine (i.e., existing source) unable to operate in compliance with the standard prescribed under this subpart or lacking sufficient information to apply for an alternative standard within 90 days of the effective date of the standard may request a waiver of compliance with

such standard for a period not exceeding two years from the effective date. Any request shall be in writing and shall include the following information:

(1) The reasons for requesting the waiver;

(2) A schedule for achieving compliance with the standard, or if applicable, the alternative standard, including the steps which will be taken to come into compliance including a date by which each step will be achieved; and

(3) Interim emission control steps will be taken during the waiver period.

(c) Changes in the information provided under paragraph (a) of this section shall be provided to the Administrator within 30 days after such change, except that if changes will result from modification of the source, as defined in §§ 61.02, the provisions of § 61.07 and 61.08 are applicable.

[FR Doc. 85-9200 Filed 4-16-85; 8:45 am]

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Federal Register

Wednesday
April 17, 1985

Part VI

Department of the Interior

Fish and Wildlife Service

50 CFR Parts 13 and 17 Importation of Green Sea Turtle Parts and Products; Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Parts 13 and 17

Importation of Green Turtle Parts and Products

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Response to petition for rulemaking; proposed rule.

SUMMARY: The Cayman Islands Government, on behalf of the Cayman Turtle Farm, Ltd., has petitioned the Fish and Wildlife Service to amend the existing prohibition on importation into the United States of the parts and products of green sea turtles (*Chelonia mydas*). In response, the Service proposes to amend the existing regulations applicable to trade in green sea turtle parts and products. The proposed rule would allow importation of green sea turtle parts and products derived from populations approved for such trade by the Parties to the Convention on International Trade in Endangered Species of Wild Fauna and Flora and by the Director of the Service. The proposed rule would allow neither trade in live green sea turtles nor taking of green sea turtles from the wild.

DATE: Public comments will be accepted until June 7, 1985.

ADDRESSES: Comments may be mailed to Director (LE), Fish and Wildlife Service, P.O. Box 28006, Washington, D.C. 20005, or delivered to the Division of Law Enforcement, Fish and Wildlife Service, 3rd Floor, 1375 K Street, NW., Washington, D.C., between the hours of 8:00 a.m. and 4:00 p.m. Comments should bear the identifying notation REG 17-02. All materials received, including the Cayman Islands' Petition, may be inspected weekdays during normal business hours at the Office of the Service's Division of Law Enforcement, 3rd Floor, 1375 K Street NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Kathleen King, Enforcement Specialist, Branch of Investigations, Division of Law Enforcement, Fish and Wildlife Service, U.S. Department of the Interior, P.O. Box 28006, Washington, D.C. 20005. Telephone (202) 343-9242.

SUPPLEMENTARY INFORMATION:**Background**

The green sea turtle is a species listed pursuant to the Endangered Species Act of 1973, as amended, 16 U.S.C. 1531-1543. The green sea turtle is listed as threatened, except for certain populations that are listed as

endangered. 50 CFR 17.11. Species listed as threatened generally are subject to regulations that allow importation only pursuant to permit, for noncommercial purposes and under extremely limited circumstances. 50 CFR 17.21 and 17.31. The Service may, however, promulgate special regulations for a species or population listed as threatened. 16 U.S.C. 1533(d); 50 CFR 17.31(c). On July 28, 1978, the Service and the National Marine Fisheries Service jointly issued special regulations that, among other things, prohibit all importation of the green sea turtle. 43 FR 32800; 50 CFR 17.42(b), 227.71 and 227.72. The Cayman Turtle Farm, Ltd. (CTF), which operates a mariculture operation in the Cayman Islands where it breeds green sea turtles for scientific purposes, challenged the regulations. A federal court ruled, however, that the omission of a mariculture exemption was within the agencies' authority under the Endangered Species Act, was not precluded by the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), and was adequately supported by the administrative record. *Cayman Turtle Farm, Ltd. v. Andrus*, 478 F. Supp. 125 (D. D.C. 1979).

The green sea turtle is also listed on Appendix I to CITES. See 50 CFR 23.23. CITES provides that species listed on Appendix I may only be traded if they are accompanied by import and export permits that may only be issued under certain conditions. Art. III, ¶ 2.3; 50 CFR Part 23, Subpart B. An import permit may only be issued if, among other things, the import will be for purposes that are not detrimental to the survival of the species and not primarily commercial. Art. III, ¶ 3(a), (c). Species listed on Appendix II to CITES may be traded if the country of export issues a permit for their shipment. Art. IV, ¶ 2. Under certain conditions a population of a species listed on Appendix I may be deemed to be included on Appendix II and thus be subject to the less restrictive permit requirements applicable to Appendix II species. For instance, Article VII, Paragraph 4 of CITES provides, among other things, that specimens of animal species included in Appendix I that are bred in captivity for commercial purposes shall be deemed to be included on Appendix II. Conf. 2.12, a resolution adopted by the Parties to CITES in 1979, confirms that such specimens are subject to the export permit and other provisions of Article IV. Another example is Conf. 3.15, which was adopted by the Parties in 1981. Conf. 3.15 allows a population of species included in Appendix I to be included in Appendix II if the population

is no longer endangered and would benefit by ranching. Ranching is defined to mean the rearing in a controlled environment of species taken from the wild.

By letter dates May 24, 1984, the government of the Cayman Islands submitted to the Secretary of the Interior a petition to amend 50 CFR Part 17 in order to allow importation and reexportation of green sea turtle parts and products and their trade in interstate and foreign commerce. The requested regulatory amendment would apply only to parts and products of members of a population listed on Appendix II of CITES or to an operation that, in the judgment of the Secretary, is entitled to the bred in captivity exception in Article IV, Paragraph 4 of CITES or otherwise qualifies under CITES for international trade for commercial purposes.

The United Kingdom has filed a proposal on behalf of the Cayman Island that would allow the transfer of the green sea turtle population maintained by CTF from Appendix I to Appendix II and allow trade in parts and products of that population. This proposal has been submitted for approval at the Fifth Meeting of the Conference of the Parties to CITES to be held in Buenos Aires, Argentina from April 22 through May 3, 1985. Similar proposals have been submitted by Surinam and Reunion. The United States will participate in this Meeting as a Party to CITES.

The Service's Wildlife Permit Office, which is the Management Authority of the United States designated in accordance with Article IX of CITES, is preparing negotiating positions with respect to each proposal that will be presented to the Conference of the Parties to CITES in Buenos Aires. The proposed negotiating position of the United States with respect to the various green sea turtle proposals that will be before the Parties to CITES in Buenos Aires is that the United States will amend its regulations to allow import and trade for commercial purposes of green sea turtle parts and products derived from populations removed by the Parties to CITES from Appendix I and/or listed on Appendix II or III. The final negotiating positions of the United States will be announced before April 22, 1985.

The Proposed Rule

In response to the rulemaking petition submitted by the Government of the Cayman Islands the Service proposes to amend 50 CFR Parts 13 and 17 to allow for import and commercial trade in green sea turtle parts and products

derived from green sea turtle populations that, as a result of action by the Parties to CITES, have been removed from Appendix I listed on Appendix II or III. The Service will not issue a final rule unless the Conference of the Parties to CITES approve at least one of the proposals dealing with listing and trade in green sea turtle parts and products, and will not issue a final rule earlier than 90 days following the Buenos Aires meeting, when any amendment to Appendices I and II would become effective. CITES Art. XV, ¶ 1(c).

Section 4(d) of the Endangered Species Act, 16 U.S.C. 1533(d), requires that the Service shall issue regulations for threatened species as it "deems necessary and advisable to provide for the conservation of the species." The Service believes that any proposal to move a particular green sea turtle population from Appendix I that is approved by the Parties to CITES would meet this standard. Approved ranching operations must, for instance, "be primarily beneficial to the conservation of the local population" and "have no significant detrimental impact on wild populations." Conf. 3.15. Approved bred in captivity operations must be "established in a manner not detrimental to the survival of the species in the wild." Conf. 2.12.

In declining to include a mariculture exemption in 50 CFR 17.42(b) when it was first promulgated in 1978, the Service advanced several supporting arguments. The Service found that (1) trade in commercial mariculture products would have a deleterious impact upon wild sea turtle populations, (2) measures to enforce compliance with the exemption were inadequate to avoid threats to the wild populations, (3) the scientific research benefits from the exemption did not outweigh the risks to survival of the wild populations, and (4) the Cayman Turtle Farm was not totally independent of wild eggs and turtles. The court in *Cayman Turtle Farm, Ltd. v. Andrus, supra*, ruled that each of these findings had support in the administrative record of the rulemaking. The Service does not, however, believe that these findings are applicable to the current rulemaking. Each of the four factors that militated against granting a mariculture exemption in the 1978 rulemaking referred to a potential adverse impact on wild populations of green sea turtles. The proposed rule, on the other hand, would effectively require a finding that wild populations would not be harmed prior to commencement of commercial import and trade in green sea turtle parts and products. As noted

above, Conf. 2.12 and 3.15, which became effective subsequent to the 1978 rulemaking and the *Cayman Turtle Farm* decision, require that approved ranching and bred in captivity operations not operate to the detriment of wild populations. The proposed rule thus would allow imports only from an operation found by the Parties to CITES to operate without detriment to wild populations. In addition, the Service believes that the permit and marking system set out in the proposed rule would ensure compliance with the rule to avoid illegal imports of wild green sea turtle parts and products.

The proposed rule consists primarily of the addition of a new subparagraph (c) to 50 CFR 17.42. The sea turtle special rule in 50 CFR 17.42(b) would apply as in the past except that it would not apply to populations of green sea turtle special listed in 50 CFR 17.11. These populations, which would have to be approved by the Parties to CITES for removal from Appendix I and/or inclusion on Appendix II or III, would instead be subject to the provisions of proposed 50 CFR 17.42(c), provided that the Director of the Service also approved their special listing in 50 CFR 17.11.

Proposed 50 CFR 17.42(c) would allow import and trade in green sea turtle parts and products but would not authorize import and trade in live turtles and takings of green sea turtles from the wild. Any commercial importation of or other commercial trade in green sea turtle parts and products would be allowed to take place only pursuant to a special permit issued in accordance with proposed 50 CFR 17.42(c)(4). In addition, imported or commercially traded green sea turtle parts and products would have to be marked and identified in accordance with proposed 50 CFR 17.42(c)(5).

Determination of Effects

The Department of the Interior has determined that the proposed rule is not a major rule under Executive Order 12291. The Department has also certified that the proposed rule will have no significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq. These determinations are discussed in more detail in a "Determination of Effects" which has been prepared by the Service. A copy of that document may be obtained by contacting the person identified above under "FOR FURTHER INFORMATION CONTACT."

Paperwork Reduction Act

The collection of information requirements contained in the proposed rule, including the maintenance and retention of records and the application for permits, has been submitted to the Office of Management and Budget for review under 44 U.S.C. 3504(h) of the Paperwork Reduction Act. Comments concerning these requirements should be directed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Interior Desk Officer, Room 3201, Washington, D.C. 20503. The information collection requirements contained in proposed 50 CFR 17.42(c) that relate to marking and labeling of the parts and products of the specially listed population do not require approval of the Office of Management and Budget under 44 U.S.C. 3501 et seq., because there are fewer than ten respondents annually.

Natural Environmental Policy Act

A draft Environmental Assessment has been prepared in conjunction with this proposed rule. It is on file with the Division of Law Enforcement, U.S. Fish and Wildlife Service, 3rd Floor, 1375 K Street NW., Washington, D.C. 20005, and may be examined during regular business hours. Single copies are also available upon request by contacting the person identified above under "FOR FURTHER INFORMATION CONTACT."

List of Subjects

50 CFR Part 13

Administrative practice and procedure, Exports, Fish, Imports, Penalties, Reporting requirements, Wildlife.

50 CFR Part 17

Endangered and threatened wildlife, Fish, Marine mammals, Plants (Agriculture).

Regulation Promulgation

For the reasons set out in the preamble, Subchapter B, Chapter I of Title 50 *Code of Federal Regulations* is proposed to be amended as follows:

PART 13—[AMENDED]

1. Authority for Part 13:

Authority: 18 U.S.C. 42; sec. 4, Pub. L. 97-79, 95 Stat. 1074 (16 U.S.C. 3373); sec. 7, Pub. L. 97-79, 95 Stat. 1078 (16 U.S.C. 3376); sec. 3, Pub. L. 65-186, 40 Stat. 755 (16 U.S.C. 704); sec. 3(h)(3), Pub. L. 95-616, 92 Stat. 3112 (16 U.S.C. 712); sec. 2, 54 Stat. 251, as amended by sec. 9, Pub. L. 95-616, 92 Stat. 3114 (16 U.S.C. 668a); sec. 102, 76 Stat. 73 (19 U.S.C. 1201, "Schedule 1, Part 15D, Headnote 2(1)).

Tariff Schedules of the United States"; sec. 9(d), Pub. L. 93-205, 87 Stat. 893 (16 U.S.C. 1538(d)); sec. 6(a)(1), Pub. L. 90-159, 93 Stat. 1228 (16 U.S.C. 1537a); E.O. 11911, 41 FR 15683, 3 CFR, 1976 Comp., p. 112, sec. 101, Pub. L. 93-205, 87 Stat. 896, as amended by secs. 2 and 3, Pub. L. 94-359, 90 Stat. 3760; sec. 7, Pub. L. 95-359, 90 Stat. 911 and 912; sec. 5, Pub. L. 95-632, 92 Stat. 3760; sec. 7, Pub. L. 96-159, 93 Stat. 1230 (16 U.S.C. 1539); sec. 11, Pub. L. 93-205, 87 Stat. 897, as amended by sec. 6(4), Pub. L. 95-632, 92 Stat. 3761 (16 U.S.C. 1540(b)(2)(f)); sec. 13(d), 86 Stat. 905, amending 85 Stat. 480 (16 U.S.C. 742j-1); Title I amended by Title II sec. 201(e), Pub. L. 96-470, 94 Stat. 2241 (16 U.S.C. 1382); 65 Stat. 290 (31 U.S.C. 483(a)).

Source: 39 FR 1161, Jan. 4, 1974, unless otherwise noted.

2. § 13.11(b)(2) is revised to read as follows:

§ 13.11 [Amended]

(b) * * *

(2) Exception to designated port (50 CFR Part 14), import/export license (50 CFR 14.93), special listed population trade (50 CFR 17.42), migratory bird permit, other than banding (50 CFR Part 21) and bald or golden eagle permits (50 CFR Part 22)—special agent in charge of the law enforcement district in which the applicant resides or maintains its principal place of business if the applicant is a corporation or business, or, if the applicant is a foreign national, business, or corporation, in which the resident agent designated to accept service of legal process and to maintain records, resides, or maintains its principal place of business. (See 50 CFR 10.22 for addresses and boundaries of the law enforcement districts).

3. Amend § 13.11, paragraph (d)(4) by adding under the column Type of Permit the words "Special Listed Population—Trade, (Part 17)" and under the column Fee the figure "\$100."

4. § 13.12 [Amended]

(b) Amend § 13.12, paragraph (b) by adding under the topic Type of Permit, the words "Special Listed Population—Trade" and under the topic Section, the entry "§ 17.42."

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

5. Authority for Part 17.

Authority: Pub. L. 93-205, 87 Stat. 894; Pub. L. 94-359, 90 Stat. 911; Pub. L. 95-632, 92 Stat. 3751; Pub. L. 96-159, 93 Stat. 1225; Pub. L. 97-304, 96 Stat. 1411 (16 U.S.C. 1531, et seq.), unless otherwise noted.

6. Section 17.11(h) is amended by inserting the following entry into the table under appropriate column headings:

§ 17.11 [Amended]

Common name	Scientific name	Historic range	Veterate population where endangered or threatened	Status	Where issued	Critical habitat	Specific rules
Turtle, green sea.	<i>Chelonia mydas</i>	Circumglobal in tropical and temperate seas and oceans.	Wherever found except where listed as threatened special listed captive population or endangered below.	T	42	NA	17.42(b) Parts 220 and 227.
Turtle, green sea.	<i>Chelonia mydas</i>	Captive population held in Reunion, Surinam, Grand Cayman Is.	Special listed captive population held in Reunion, Surinam, and Grand Cayman Is.	T		NA	17.42(c).

7. Section 17.42(b) is revised as shown below:

§ 17.42 [Amended]

(b) Green sea turtle (*Chelonia mydas*), loggerhead sea turtle (*Caretta caretta*), olive ridley sea turtle (*Lepidochelys olivacea*) (these do not include the populations listed as endangered in § 17.11 or the populations of green sea turtle subject to regulation as special listed populations in § 17.42(c).)

8. A new § 17.42(c) is added to read as follows:

(c) Green sea turtle (*Chelonia mydas*). Special listed populations.

(1) *Scope.* The regulations of this subparagraph (c) are a special rule which apply only to trade in parts and products derived from populations of the green sea turtle (*Chelonia mydas*) approved for delisting from Appendix I or listed on Appendix II or III as a result of an action by the Parties, Convention on International Trade in Endangered Species of Wild Fauna and Flora, and approved by the Director. These regulations do not apply and do not permit trade in live specimens of green sea turtle (*Chelonia mydas*) which shall continue to be subject to the full protection of the most restrictive listing applicable to the specimen and in particular to the regulations and exceptions in §§ 17.21, 17.31, 17.42(b) and 227.72.

(2) *Definitions.* As used in this special rule:

"Identification Number" means a unique number identifying product unit by country, product registration number and year of craft e.g. KYO1/85, KY represents the Cayman Islands utilizing the two letter code to be included in 50 CFR Appendix A, Chapter I, 01

represents the item registration number and 85 represents the year.

"Label" is an affixation to or markings made using silk screen or other process using permanent inks or dyes placed directly on a manufactured article or container giving information as to the nature, quality, numbers, weight, or the contents of a package or container, name of the maker, and any other information.

"Master Carton" is a unit, package or container for sea turtle parts or products which is the smallest unit of that specific part or product to be imported. Regardless of dimensions, the master carton is constructed of materials and in a manner or form so that, once closed, sealed, or packaged in the country of origin of the sea turtle from which the part or products were derived, the master carton cannot be opened without physical and readily visible destruction of the integrity of the carton itself. While the master carton may contain smaller packages of sea turtle parts or products, those smaller packages or the products are not eligible for import except within the exception for noncommercial importations as personal accompanying baggage.

"Product" is anything manufactured, produced, fabricated or crafted from or by human or mechanical effort, resulting from a natural process, or part of specimens included in a specially listed population from an operation approved pursuant to CITES Resolutions and does not include live specimens.

"Product Unit" means the smallest item of each sea turtle part and product that will be individually marked and entered into trade.

"Primary Container" means any container used to wrap or otherwise immediately to contain sea turtle parts or products.

"Uniform Marking System" means a system of marking each product unit approved by the Parties, Convention on International Trade in Endangered Species for a specially listed population of a species which as a minimum includes the International Organization for Standardization code for the country of origin, a unique identification number and the year of production, or if for product units on hand or manufactured from products of the operation on hand at the time the proposal for special listing of that species was approved by CITES.

(3) **Prohibitions.** The following prohibitions apply to all parts and products of green sea turtle (*Chelonia mydas*) subject to this subparagraph:

(i) **Import.** No person may import green sea turtle (*Chelonia mydas*) parts and products except parts and products marked and identified in accordance with this special rule and imported from the country of origin or a nonproducing country approved by the Service which is also without an indigenous population of green sea turtle (*Chelonia mydas*) listed as endangered pursuant to 50 CFR Part 17 or on Appendix I to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (50 CFR Part 23). (i) Any natural person may import as a noncommercial importation as part of personal accompanying baggage only properly marked and identified items of polished shell, shell products, finished cosmetic products, and leather goods when each item is marked by the producing country and accompanied by valid documentation stating that the item is a part or product of that producing country's approved ranch or otherwise specially listed population of green sea turtle (*Chelonia mydas*). (ii) Any importation that is not a noncommercial importation as defined by § 17.42(c)(3)(a)(i) is a commercial importation of green sea turtle and shall only be imported pursuant to special permit issued by the Service pursuant to subparagraph (4).

(ii) **Export or Re-export.** Export or re-export of green sea turtle (*Chelonia mydas*) parts or products subject to this special rule is prohibited.

(iii) **Commercial Transactions Other Than Importations.** No person may deliver, receive, carry, transport or ship by any means whatsoever or may sell (except at retail to the final and ultimate consumer of the part or product), purchase (except at retail as the final and ultimate consumer), or offer for sale or purchase, any parts or products of green sea turtle (*Chelonia mydas*) which have been imported subject to this special rule except pursuant to special

permit issued under conditions of 50 CFR Part 13 and in accordance with subparagraph (4).

(4) **Permits.** In addition to the general conditions set forth in Part 13 of this chapter, each permit issued under this special rule is subject to the following special conditions.

(i) Permits, except for permits in accordance with § 17.32 are not available for live specimens of green sea turtles (*Chelonia mydas*);

(ii) The application for a special permit must be submitted to and approved by the Director by the person who wishes to engage in any commercial activity related to green sea turtle (*Chelonia mydas*) parts or products from a specially listed population and must be submitted on an official application form (Form 3-200) provided by the Service. The application shall contain as an attachment the following information:

(A) The name, and address of the applicant. If the applicant is a business or corporation, whether foreign or domestic, the application shall designate a resident agent for the applicant listing the name and correct address of the agent and shall provide that the resident agent is appointed and designated to receive and accept on behalf of the applicant all legal process related to the enforcement of these regulations; any permit issued under this subchapter shall lapse and be void if at any time a business or corporation, foreign or domestic, fails to be represented by a duly appointed and acting resident agent. The Director shall be notified immediately and in writing of any change in the name and/or address of the resident agent;

(B) The category or categories of commercial activity for which the permit is to be issued whether import, manufacture or fabrication, wholesale, or retail;

(C) A description of the applicant's business organization and the location, including the address and description of the physical plant in which any manufacture, fabrication, wholesale or retail activity will occur or the ports at which import will occur;

(D) The name and address and telephone number of the custodian of all records, books, and inventories required by this special rule or any other regulation and an agreement that all such books, records, and inventories, including actual merchandise, shall be available for inspection by Service officials at any reasonable time;

(E) A complete inventory of any and all specimens, parts or products of sea turtles on hand at the time of the application listing the specimens, parts

and products by number and/or weight and by species; and,

(F) A statement that the application and all information contained in it or any attachment is true and correct under penalty of perjury.

(iii) The permit for commercial transaction in specially listed populations shall be subject to the following conditions:

(A) Only a permittee who possesses a permit issued under the provisions of this subparagraph and valid for the category of importation may import into the United States for purposes of sale, barter, carriage, transportation or shipment or other commercial activities, including manufacture or fabrication, parts or products of green sea turtle (*Chelonia mydas*) from a specially listed population;

(B) A permittee may not manufacture or fabricate in any way a part or product of green sea turtle (*Chelonia mydas*) except one from a special listed population which was imported, purchased, sold, bartered, carried, transported, shipped or otherwise acquired in the course of a commercial activity except in accordance with a permit issued under provisions of this paragraph and valid for the category of manufacture or fabrication.

(C) A permittee may not buy a part or product of green sea turtle (*Chelonia mydas*) except from one holding a permit issued under provisions of this paragraph and valid for the category of wholesale or retail trade;

(D) A permittee may not sell, barter, offer to sell or barter, deliver, transport, carry or ship by any means whatsoever, a part or product or an item manufactured or fabricated from the part or product of the green sea turtle (*Chelonia mydas*) of a special listed population imported subject to this rule except to one who holds a permit issued under provisions of this paragraph and valid for the categories and wholesale or retail trade except that a retail sale of a part or product or of an item manufactured or fabricated from a part or product of green sea turtle of a special listed population subject to this rule may be sold to, and delivered or transported by, a retail purchaser who is the final and ultimate consumer of the part, product, or manufactured or fabricated item;

(E) A permittee may not violate any State, Federal, or foreign law or regulation concerning any specimen, part or product of green sea turtle (*Chelonia mydas*);

(F) A permittee must maintain complete and accurate inventory control of all specimens, parts, products, or

items manufactured or fabricated from parts or products of the green sea turtle (*Chelonia mydas*) including the residue or detritus of any manufacturing or fabricating process and must maintain accurate and complete bookkeeping records in accordance with the requirements of § 13.46 of this Chapter for all transactions related to the acquisition or disposition of parts or products of the green sea turtle (*Chelonia mydas*) in the permittee's possession at any time. For all transactions involving the green sea turtle or any species of sea turtle the permittee must maintain on file a copy of the permit or other document required or issued pursuant to Part 23 of this Chapter or any other document issued by a State, Federal or foreign government related to transactions in the parts or products of green sea turtle.

(G) The permittee holding a permit valid for the category of import must file on or before March 31 of each year a written report, certified under penalty of perjury, in English, of all transactions during the preceding calendar year ending December 31 involving the green sea turtle (*Chelonia mydas*) and other species of sea turtles including the number of parts and products or the weight of such parts or products on hand at the beginning and end of the accounting period, the number of transactions in each type of part and product, and the number of parts or products involved in each transaction or the weight of the part or product of sea turtle in each transaction.

(H) A permittee may not transport, ship, carry, deliver or otherwise transport by any means whatsoever any part or product or any item manufactured or fabricated from the part or product of green sea turtle (*Chelonia mydas*) subject to this rule unless such part, product or item is packaged in a master carton and tagged or labeled in a manner that indicates that the part, product, item, or any package containing parts, products or items of green sea turtle (*Chelonia mydas*); the quantity of the part or product enclosed in a package, if any; the name and address of the seller or consignor, and of the manufacturer or fabricator if the item is one made from parts or products of the green sea turtle (*Chelonia mydas*).

(I) A special permit for specially listed populations shall be valid only for one year from the date of issuance and must be renewed annually by appropriate application to the Director. Any failure to comply with any special condition of the permit, including a failure to maintain a designated resident agent,

shall result in the nonrenewal of the permit.

(5) *Marking and identification.* Only the parts or products listed of the green sea turtle, marked, identified, and packaged in a master carton, in accordance with this subparagraph shall be eligible for import for commercial purposes or for other commercial transaction after importation. Properly marked, identified, and packaged parts and products, when transported or shipped in interstate commerce by a permittee shall not require any additional permit from the Service.

(i) *Edible products.* The unit of edible products to be imported into the United States shall be the master carton. Each master carton, whatever the physical dimensions, shall contain no more than 50 pounds gross weight of edible product. Each master carton shall be labeled with the producer's name and address, a correct description of the edible product contained in the carton and the product weight, and the complete identification number for the carton. The identification number of each master carton shall be reflected on all business documents, including invoices, and on all import or export documents or certificates. Each master carton shall be sealed upon closure by the producer and shall be so constructed that it cannot be opened without destruction of the sealing material or device. Only the following edible products, packaged in separate master cartons, may be imported:

(A) Fillet or chunk steaks of a weight not to be less than 3 oz. per fillet or chunk. Each fillet or chunk shall be individually wrapped in a wrapper reflecting the producer's name and the country of origin code;

(B) Steak pieces may be shipped in bulk packages but shall be contained within a sealed wrapper in the master carton. The wrapper shall reflect the producer's name and country of origin code and shall be of such material and construction that it cannot be opened without destruction of the sealing material or device;

(C) Calipee or calipash, a cartilaginous product, shall be packaged only in bulk, contained within a sealed wrapper in the master carton. The wrapper shall reflect the producer's name and the country of origin code. Each wrapper shall be of material and construction that it cannot be opened without destruction of the sealing material or device;

(D) Neck and tail bones shall be packaged only in bulk, contained in a sealed wrapper in a master carton. The wrapper shall reflect the producer's

name and country of origin code. Each wrapper shall be of such material and construction that it cannot be opened without destruction of the sealing material or device;

(E) Whole or skinned flipper may be packaged only in bulk, contained in a sealed wrapper in a master carton. The wrapper shall reflect the producer's name and country of origin code. Each wrapper shall be of such material and construction that it cannot be opened without destruction of the sealing material or device;

(ii) *Decorative Products.* The smallest product unit of decorative products made of green sea turtle parts to be imported shall be as defined by each product listed below:

(A) *Whole polished shells.* Each shell shall be labeled with the producer's name and a complete identification number. Each label would be made of tamper evident material which would be destroyed if removed from the product. Any packaging of a shell or shells shall be in a carton printed with the producer's name, address, product description and weight, and listing all shell identification number(s) for enclosed shells. Each shell's identification number shall be listed on all invoices, and all import or export documents or certificates.

(B) *Scutes.* Scutes or portions of shell shall be bulk packaged in master cartons of 50 lbs. net weight. Each master carton shall reflect the producer's name and address and a complete identification number. Each identification number for each carton of scute shall be listed on all invoices and all import or export documents or certificates.

(C) *Shell shapes.* Shell shapes which are processed parts of the whole turtle shell shall be packaged in bulk, in packages containing no more than 5 lbs. per package. Each package shall be wrapped in a wrapper reflecting the producer's name and country of origin code. Packages shall be sealed by the producer and shipped in a master carton, of a gross weight of 50 lbs., constructed so that it cannot be opened without destruction of the sealing material or device. All master cartons shall be labeled with the producer's name and address, a correct description of the contents and product weight and the complete identification number of the carton.

(D) *Jewelry.* Jewelry shall be labeled with a complete identification number and accompanied by individual documentation listing the identification number for each piece. If the item is too small for one class of the complete

identification number, it shall be labeled with the country of origin code and sealed by the producer in a wrapper bearing the producer's name, a product description and the complete identification number for the wrapped jewelry. The wrapper shall be of such material and construction so that it cannot be opened without destroying the wrapper.

(E) *Finished leather goods* shall be individually labeled with the producer's name and a complete identification number. Each item shall be accompanied by documents listing the identification number for each item.

(iii) *Skins*. Skins of the green sea turtle may be imported only as salted or unfinished hides or pieces. Each hide piece shall be labeled with the country of origin code. Hide pieces may be packaged in a bag containing no more than 50 lbs. and sealed by a seal numbered with the complete identification number for that bag. The

seal shall be fixed and of such material that it must be destroyed in order to open the bag. Bags may be packed in larger crates labeled with the producer's name, address, and product name, identification, weight, and the identification numbers of all bags contained in the crate.

(iv) *Oil and Cosmetics*. Oil produced and cosmetics manufactured from the green sea turtle shall be eligible for import only as follows:

(A) *Oil* may only be packaged in 55 gallon metal drums holding no more than 400 lbs. net weight. All drums shall be sealed with press-on metal covers constructed and affixed so that the corner must be destroyed to be removed. Each drum shall be labeled with the producer's name, address, the product description, and shall be individually numbered with a complete identification number for each drum.

(B) *Cosmetics*. Finished cosmetics shall be sealed in primary containers by

the producer and shall be clearly labeled giving product name, the producing company, and shall state that any oil in the cosmetics was obtained from specially listed sea turtles. Primary containers may be shipped in larger, sealed master cartons containing no more than twelve primary containers of any item. Each master carton shall be sealed by the producer and labeled with the producer's name and address, a complete description and list of primary containers enclosed and shall bear a complete identification number. The identification number for each master carton shall be reflected on all invoices and all import or export documents or certificates.

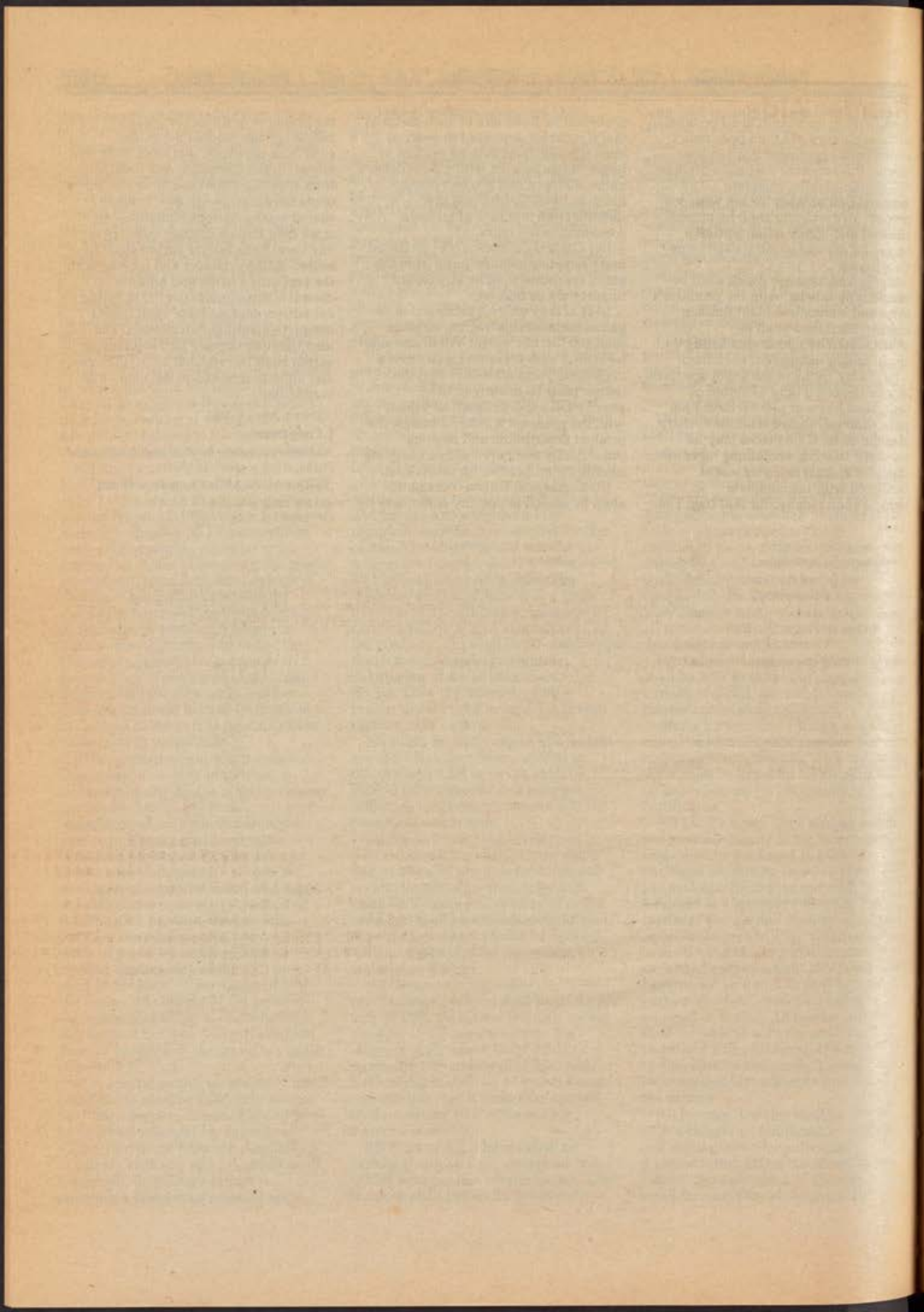
Dated: April 5, 1985.

J. Craig Potter,

Assistant Secretary for Fish and Wildlife and Parks.

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H.J. Res. 74 / Pub. L. 99-20

To designate the week of September 8, 1985, as "National Independent Retail Grocer Week". (Apr. 14, 1985; 99 Stat. 44) Price: \$1.00

S.J. Res. 35 / Pub. L. 99-21

To authorize and request the President to issue a proclamation designating April 21 through April 27, 1985, as "National Organ Donation Awareness Week". (Apr. 14, 1985; 99 Stat. 45) Price: \$1.00

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